HEALTH TECHNOLOGY ASSESSMENT

VOLUME 17 ISSUE 21 MAY 2013
ISSN 1366-5278

A cluster randomised controlled trial of a manualised cognitive–behavioural anger management intervention delivered by supervised lay therapists to people with intellectual disabilities

P Willner, J Rose, A Jahoda, B Stenfert Kroese, D Felce, P MacMahon, A Stimpson, N Rose, D Gillespie, J Shead, C Lammie, C Woodgate, JK Townson, J Nuttall, D Cohen and K Hood

DOI 10.3310/hta17210

National Institute for
Health Research

A cluster randomised controlled trial of a manualised cognitive–behavioural anger management intervention delivered by supervised lay therapists to people with intellectual disabilities

P Willner,[1]* J Rose,[2] A Jahoda,[3] B Stenfert Kroese,[2]
D Felce,[4] P MacMahon,[3] A Stimpson,[5] N Rose,[2]
D Gillespie,[6] J Shead,[2] C Lammie,[3] C Woodgate,[5]
JK Townson,[6] J Nuttall,[6] D Cohen[7] and K Hood[6]

[1]Department of Psychology, Swansea University, Swansea, UK
[2]School of Psychology, University of Birmingham and Black Country Partnership Foundation Trust, Birmingham, UK
[3]Institute of Health and Wellbeing, College of Medical, Veterinary and Life Sciences, University of Glasgow, Gartnavel Royal Hospital, Glasgow, UK
[4]Psychological Medicine, School of Medicine, Cardiff University, Cardiff, UK
[5]Abertawe Bro Morgannwg University Health Board, Swansea, UK
[6]South East Wales Trials Unit, Cardiff University, Cardiff, UK
[7]Faculty of Health, Sport and Science, University of Glamorgan, Pontypridd, UK

*Corresponding author

Declared competing interests of authors: none

Published May 2013
DOI: 10.3310/hta17210

This report should be referenced as follows:

Willner P, Rose J, Jahoda A, Stenfert Kroese B, Felce D, MacMahon P, *et al.* A cluster randomised controlled trial of a manualised cognitive–behavioural anger management intervention delivered by supervised lay therapists to people with intellectual disabilities. *Health Technol Assess* 2013;**17**(21).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents*®/Clinical Medicine.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.596

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed ‘systematic’ when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/53/34. The contractual start date was in May 2009. The draft report began editorial review in May 2012 and was accepted for publication in August 2012. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

© Queen’s Printer and Controller of HMSO 2013. This work was produced by Willner *et al*. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Health Sciences, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Dr Tom Marshall Reader in Primary Care, School of Health and Population Sciences, University of Birmingham, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Honorary Professor, Business School, Winchester University and Medical School, University of Warwick, UK

Professor Jane Norman Professor of Maternal and Fetal Health, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, NICE, UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professorial Research Associate, University College London, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk

Abstract

A cluster randomised controlled trial of a manualised cognitive–behavioural anger management intervention delivered by supervised lay therapists to people with intellectual disabilities

P Willner,[1]* J Rose,[2] A Jahoda,[3] B Stenfert Kroese,[2] D Felce,[4] P MacMahon,[3] A Stimpson,[5] N Rose,[2] D Gillespie,[6] J Shead,[2] C Lammie,[3] C Woodgate,[5] JK Townson,[6] J Nuttall,[6] D Cohen[7] and K Hood[6]

[1]Department of Psychology, Swansea University, Swansea, UK
[2]School of Psychology, University of Birmingham and Black Country Partnership Foundation Trust, Birmingham, UK
[3]Institute of Health and Wellbeing, College of Medical, Veterinary and Life Sciences, University of Glasgow, Gartnavel Royal Hospital, Glasgow, UK
[4]Psychological Medicine, School of Medicine, Cardiff University, Cardiff, UK
[5]Abertawe Bro Morgannwg University Health Board, Swansea, UK
[6]South East Wales Trials Unit, Cardiff University, Cardiff, UK
[7]Faculty of Health, Sport and Science, University of Glamorgan, Pontypridd, UK

*Corresponding author p.willner@swansea.ac.uk

Background: Anger is a frequent problem for many people with intellectual disabilities, and is often expressed as verbal and/or physical aggression. Cognitive–behaviour therapy (CBT) is the treatment of choice for common mental health problems, but CBT has only recently been adapted for people with intellectual disabilities. Anger is the main psychological presentation in which controlled trials have been used to evaluate CBT interventions for people with intellectual disabilities but these do not include rigorous randomised studies.

Objectives: To evaluate (1) the impact of a staff-delivered manualised CBT anger management intervention on (a) reported anger among people with mild to moderate intellectual disabilities, and (b) anger coping skills, aggression, mental health, quality of life and costs of health and social care; (2) factors that influence outcome; and (3) the experience of service users, lay therapists and service managers.

Design: A cluster randomised controlled trial based on 30 day centres (15 intervention and 15 control). Intention-to-treat comparisons of outcomes used a two-level linear regression model to allow for clustering within centres with baseline outcome levels as a covariate. Comparison of cost data used non-parametric bootstrapping. Qualitative analysis used interpretative phenomenological analysis and thematic analysis.

Setting: Recruited day centres had four-plus service users with problem anger who were prepared to participate, two-plus staff willing to be lay therapists, a supportive manager and facilities for group work, and no current anger interventions.

Participants: A total of 212 service users with problem anger were recruited. Thirty-three were deemed ineligible (30 could not complete assessments and three withdrew before randomisation). Retention at follow-up was 81%, with 17 withdrawals in each arm. Two to four staff per centre were recruited as lay therapists. Eleven service users, nine lay therapists and eight managers were interviewed.

Interventions: The manualised intervention comprised 12 weekly 2-hour group sessions supplemented by 'homework'. Lay therapists received training and ongoing supervision from a clinical psychologist. Treatment fidelity, group attendance and resources used in intervention delivery were monitored.

Main outcome measures: The primary outcome was the service user-rated Provocation Index (PI), a measure of response to hypothetical situations that may provoke anger. Secondary trial outcomes were the key worker-rated PI; the service user- and key worker-rated Profile of Anger Coping Skills (PACS); the service user-rated PACS imaginal provocation test (PACS-IPT), a measure of response to actual situations known to provoke anger; aggression; mental health; self-esteem; quality of life; and health and social care resource use. Assessments were administered before randomisation and at 16 weeks and 10 months after randomisation.

Results: Fourteen treatment groups were delivered, each with 12 sessions lasting an average of 114 minutes, with a mean of 4.9 service users and 2.0 lay therapists. The mean hourly cost per service user was £25.26. The mean hourly excess cost over treatment as usual was £12.34. There was no effect of intervention on the primary outcome – self-rated PI. There was a significant impact on the following secondary outcomes at the 10-month follow-up: key worker-rated PI, self-rated PACS-IPT and self- and key worker-rated PACS. Key workers and home carers reported significantly lower aggression at 16 weeks, but not at 10 months. There was no impact on mental health, self-esteem, quality of life or total cost of health and social care. Service users, key workers and service managers were uniformly positive.

Conclusions: The intervention was effective at changing anger coping skills and staff-rated anger. Impact on self-rated anger was equivocal. With hindsight there are reasons, from an analysis of factors influencing outcomes, to think that self-rated PI was not a well-chosen primary outcome. Widespread implementation of manualised lay therapist-led but psychologist-supervised anger management CBT for people with mild to moderate intellectual disabilities is recommended.

Trial registration: Current Controlled Trials ISRCTN37509773.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 17, No. 21. See the HTA programme website for further project information.

Contents

List of abbreviations

ABC	Aberrant Behaviour Checklist
ABC-H	Aberrant Behaviour Checklist – Hyperactivity
ABC-I	Aberrant Behaviour Checklist – Irritability
ABS	Adaptive Behaviour Scale
AIC	Akaike information criterion
ANCOVA	analysis of covariance
BNF	*British National Formulary*
BPVS	British Picture Vocabulary Scale
CACE	complier-adjusted causal effect
CBS	Controllability Beliefs Scale
CBT	cognitive–behavioural therapy
CI	confidence interval
ComQoL-ID	Comprehensive Quality of Life Scale – Intellectual Disability
CSRI	Client Service Receipt Inventory
CTS-Psy	Cognitive Therapy Scale for Psychosis
FSIQ	Full Scale Intelligence Quotient
GAS	Glasgow Anxiety Scale
GCSE	General Certificate of Secondary Education
GDS	Glasgow Depression Scale
IAPT	Increasing Access to Psychological Therapies
ICC	intracluster correlation coefficient
IPA	interpretative phenomenological analysis
IPT	imaginal provocation test
IQ	intelligence quotient
IQR	interquartile range
MAGIC	Manualised Group Intervention Checklist
MOAS	Modified Overt Aggression Scale
N/A	not applicable
NVQ	National Vocational Qualification
PACS	Profile of Anger Coping Skills
PACS-IPT	Profile of Anger Coping Skills – imaginal provocation test
PI	Provocation Index
RCT	randomised controlled trial
RSES	Rosenberg Self-Esteem Scale
SD	standard deviation
TA	thematic analysis
WASI™	Wechsler Abbreviated Scale of Intelligence™

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Anger is often expressed as verbal or physical aggression. Prevalence estimates for problem anger among people with intellectual disabilities vary between 11% and 27%. Estimates for significant aggression have a similar range of 6–24%. Aggression is the main reason for an adult with intellectual disability to be seen as having severe challenging behaviour. It may lead to exclusion from services, breakdown of residential placements, involvement with the criminal justice system, adverse effects on the psychological well-being of staff and family carers, and increased costs of health and social care services that individuals receive.

Cognitive–behavioural therapy (CBT) is the treatment of choice for common mental health problems and widening access to CBT is a policy priority. However, CBT has been adapted for people with intellectual disabilities only recently and evidence of its effectiveness is not fully developed. Anger is the main psychological presentation in which controlled trials have been used to evaluate CBT interventions for people with intellectual disabilities, but rigorous randomised studies have yet to be undertaken. The current literature includes evaluations of manualised CBT, in which care staff are recruited as 'lay therapists'. There are potential advantages to this approach for ongoing support, dissemination to other staff, service commitment to the approach and efficient use of more scarce professional resources.

Objectives

The objectives of the study were to:

- evaluate the impact of a manualised CBT anger management intervention, delivered by day service staff, on reported anger among people with mild to moderate intellectual disabilities
- evaluate its effect on related outcomes, including anger coping skills, aggression, mental health and quality of life
- evaluate the extent to which similar results are observed by carers in the home setting as in day services
- analyse the extent to which service user or carer characteristics or the conduct of the intervention influence outcome
- ascertain the experience of service users, lay therapists and service managers who participate in or host the intervention
- evaluate the costs of the intervention and its impact on health and social care resource use
- develop methods in the course of the trial: (a) an instrument for monitoring the fidelity of the intervention, and (b) a self-rating version of the Profile of Anger Coping Skills (PACS) to complement third-party rating by carers.

Methods

A cluster randomised controlled trial was conducted involving 30-day services for adults with intellectual disabilities in Scotland, England and Wales. Ethical approval was granted by the South East Wales Research Ethics Committee (09/WSE03/41).

Study population, case definition and study criteria

The services that were recruited reported problem anger in at least four service users who were eligible and prepared to participate, had at least two staff willing to be trained as lay therapists, a supportive manager and facilities for group work, and were not already implementing anger interventions. Service users with mild to moderate intellectual disabilities and problem anger who wanted to improve their anger management and were able to provide informed consent and complete the assessments were recruited. Individuals receiving or urgently requiring psychological treatment for anger or aggression or considered too vulnerable to participate were excluded. A total of 212 participants were recruited, of whom 33 were deemed ineligible because they either were unable to complete the assessments ($n = 30$) or withdrew before randomisation ($n = 3$). For each service user, a key worker and, where possible, a home carer were also recruited. In each participating centre, two to four staff members were recruited to act as 'lay therapists', without reference to formal qualifications.

Baseline measures

A quality-of-life scale [Comprehensive Quality of Life Scale – Intellectual Disability (ComQoL-ID)] was administered first as it contains an assessment of the respondent's ability to use simple rating scales, the results of which were used to judge whether or not potential participants could enter the trial. Thereafter, prior to randomisation, data on sociodemographic factors, intellectual and receptive language abilities, adaptive behaviour and baseline levels of outcome measures were collected.

Randomisation

Fifteen centres were allocated to the intervention arm and 15 to a treatment-as-usual 'waiting list' control arm (to whom a similar intervention was offered following trial completion). Randomisation was performed using the method of minimisation, with a random component set at 80%. Centres were balanced on (1) their service users' average baseline self-reported Provocation Index (PI) score (see below), (2) number of service users recruited, and (3) average number of hours per week spent by the service user with at least one lay therapist outside of sessions.

Intervention

Participants in the intervention arm received a manualised CBT intervention, consisting of 12 weekly 2-hour group sessions supplemented by 'homework'. Day service staff acting as lay therapists received three training sessions on one day from a clinical psychologist, who subsequently provided them with fortnightly supervision throughout the intervention. The fidelity of the treatment provided was monitored by observation using a checklist developed for the trial. Group attendance and all resources used in delivering the intervention were recorded prospectively.

Outcome measures

The primary trial outcome was the PI as completed by the service user, a measure of felt response to defined hypothetical situations that may provoke anger. Secondary trial outcomes were the PI as completed by a key worker; the PACS, a measure of anger coping skills, as completed by the service user and a key worker; the Profile of Anger Coping Skills imaginal provocation test (PACS-IPT), a self-rated individualised measure of response to actual situations that are known to provoke anger; aggressive behaviour; mental health; self-esteem; quality of life; and health and social care resource use. Key worker-completed measures of anger, coping skills and aggression were also completed by service users' home carers to assess generalisation. A sample of service users, lay therapists and service managers were interviewed to gain their perspectives on the intervention.

Outcome assessments were administered before randomisation and in a 2-week window beginning 16 weeks after randomisation, and again in a 4-week window beginning 6 months later (i.e. 10 months after randomisation). For analysis of factors influencing outcomes, pre-intervention and 16-week follow-up data were combined in a pre–post study of the intervention and control groups, after the latter had received the intervention after the end of the trial.

Data analyses

The primary and secondary analyses were intention-to treat comparisons of outcomes (transformed to achieve normality prior to analysis where necessary) using a two-level linear regression model, to allow for clustering within centres, with participants at level 1 and centres at level 2, and with baseline levels of the outcome in question as a covariate. Non-parametric bootstrapping was used for the comparison of cost data, with a total of 5000 replications and the cluster command used to account for any correlation at service level. The pre–post data were analysed using a two-level stepwise hierarchical linear regression model.

Qualitative data from service users and lay therapists were analysed using interpretative phenomenological analysis and those from service managers using thematic analysis.

Results

Retention

One service in each arm withdrew. The overall retention rate at the 10-month follow-up was 81%, with the same number of withdrawals ($n = 17$) in the intervention and control groups.

Intervention delivery

Fourteen treatment groups were delivered, each with 12 sessions. Sessions lasted an average of 114 minutes and had on average 4.9 service users and 2.0 lay therapists. Compliance with the intervention was defined as attending 8 of the 12 sessions: 79.1% of participants who attended the 14 groups met this criterion. Fidelity monitoring suggested that lay therapists displayed a high level of group-work skills in relation to engagement of participants and appropriate presentation of information but were weakest in working with the key targets of CBT, emotions and cognitions. This was the area that best differentiated lay therapists achieving high and low levels of fidelity.

The mean hourly cost of intervention per service user was £25.26. The mean hourly excess cost of intervention over treatment as usual was £12.34.

Clinical outcomes

There was no effect of intervention on the primary outcome, self-rated PI, at the 16-week or 10-month follow-up. There was a significant impact on the following secondary outcomes at the 16-week and 10-month follow-up: key worker-rated PI, self-rated PACS-IPT, self-reported PACS and key worker-reported PACS. Key workers also reported significant reduction of aggressive behaviour at 16 weeks, but this was not maintained at 10 months. The only significant effect in home carer reports was in relation to reduced aggressive behaviour at 16 weeks. Complier-adjusted causal effect analyses tended to increase effect sizes where differences were significant but, in general, did not change non-significant findings into significant ones.

Cost outcomes

The mean total cost of health and social care resource use at the 10-month follow-up adjusted for baseline levels was £22.46 per person per week lower for the intervention group but the difference was not statistically significant.

Qualitative results

Service users

Most service users could describe the purpose of the group. Some reported being initially nervous but anxiety was short lived and the overwhelming majority of accounts were positive. Most emphasised the therapeutic value of sharing experiences and the opportunity to talk about problems. They recalled experiencing a sense of fun and enjoyment and were able to identify positive changes attributable to the intervention. Most focused on the use of newly acquired strategies – 'walking away', 'counting to ten' and 'asking for help' – which they had used successfully. They described improved relationships with peers, mood and ability to regulate arousal and they felt pride in what they had achieved.

Lay therapists

Participants felt that taking on the role of therapist was an opportunity to develop their professional knowledge and skills, enhance their support of service users, and enable their service organisation to develop. They too were initially apprehensive, worried that they lacked qualifications or might not be able to protect the time within their working week to run the group. However, they were unanimous that the training, manual and ongoing supervision equipped them to run the group and to understand group-work principles and the CBT model. They liked the manualised approach and thought that the manual was user-friendly and jargon free. Three caveats were the limited flexibility to vary session content, feeling uneasy about role play and considering more complex coping strategies to be too complicated for some group members. Participants were able to delineate skills involved in group facilitation, the management of group dynamics and the creation of a supportive therapeutic environment as critical to success. They thought that building trusting relationships with service users was the key to success. Some wanted to avoid establishing themselves as group leaders but to convey a sense of ‘all learning together’. More challenging aspects were managing the level of openness within the group and disclosure of information of a sensitive or distressing nature, engaging with service users at a level different from what was normally expected, and having to manage the personal impact of hearing emotive issues.

Managers

At the outset, managers felt that taking part was a golden opportunity to develop the service, promote multidisciplinary working, benefit from the staff training on offer, become more consistent in responding to challenging behaviour and improve outcomes for service users. Afterwards, their experience was unanimously positive. They were positive about the impact on service users and staff.

Influences on outcome

Higher service-user intelligence quotient, lower depression scores and higher self-esteem scores were associated with improved key worker PI scores, but not self-rated PI scores or PACS scores. The number of sessions attended was associated with improved self-rated PI scores, but not key worker PI and PACS scores. Younger lay therapists were associated with improved self-rated PI scores and female lay therapists with improved self-rated PACS scores. Higher intervention fidelity was associated with increased self-rated PI scores but not other outcomes.

Discussion and conclusions

Intervention content prioritised behaviour change (i.e. coping with anger) rather than cognitive change (i.e. decreasing anger per se). Significant improvements in anger coping skills were found (service user and key worker PACS). Service users did not rate their response to hypothetical anger provoking triggers differently (self-rated PI), although significant change was found in their responses to actual triggers known to make them angry (PACS-IPT). Key workers reported significant improvement in the PI. The difference between service user and key worker PI ratings may reflect the evidence from an analysis of baseline scores that the former report on their internal state and the latter respond to observed behaviour. Reported changes were associated with reduced aggression at least in the short term.

Self-rated PI was the primary outcome. However, with hindsight this may have been ill chosen owing to the behaviour change orientation of the intervention. Indeed, the findings that (1) fidelity was associated with increased self-rated PI and (2) higher fidelity reflected lay therapists doing more to create an environment in which service users felt comfortable to discuss emotional issues may mean that increased self-rated PI was a positive outcome, reflecting a greater willingness by service users to recognise and discuss their emotions.

The PACS-IPT may be a preferred measure of self-rated anger, particularly for people whose cognitive limitations make imagining hypothetical situations more difficult. However, the development of the PACS-IPT is in its infancy and further work is required to arrive at a final empirically grounded form.

The development of therapeutic as opposed to reactive approaches to challenging behaviour was welcomed by lay therapists and their managers. Although costs were not significantly affected, the relatively low cost of the intervention would mean that a small change in resource use of the order of the mean adjusted difference found here would make the intervention cost neutral in a matter of months.

Effect sizes in this study were generally smaller than those in the existing literature, although these were matched by the best-performing groups. Variability in outcome across groups would perhaps be typical of widespread routine implementation. The effect sizes found here might be a better estimate of general impact than those found earlier. However, increasing psychological input or adaptation of the content or length of the intervention to extend prior training to allow greater flexibility and to increase attention to cognitive change have the potential to increase effect sizes.

Recommendations

Manualised anger management CBT delivered by service staff given training and supervision from clinical psychologists could be used to increase anger coping skills*.* As the results were equivocal with respect to service users' felt anger per se, further research is required on the impact of the intervention in this respect and on how best to assess felt anger in people with intellectual disabilities.

If such research is conducted, the impact on costs of staff and other health and social care resource inputs should be followed up to check whether or not the development could be cost neutral.

Service users referred for anger management should be offered a mental health assessment.

Further development of the PACS-IPT is recommended.

Additional research is needed in a number of specific areas, in particular:

- how best to assess felt anger in people with intellectual disabilities
- the relationship between self-rated anger, willingness to discuss emotions and anger coping ability
- how best to select, train and supervise lay therapists
- whether or not the intervention could be improved by modifications to manual content and intervention length
- whether or not clinical psychologists would deliver the intervention more effectively than lay therapists
- clarification of the impact on health and social care costs.

Trial registration

The trial is registered as ISRCTN37509773.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Cognitive–behavioural therapy and people with intellectual disabilities

The term 'intellectual disability' (also known in the UK as 'learning disability', and formerly as 'mental retardation' or 'mental handicap') is used to describe a condition of significant impairment of both intellectual ability [usually defined as a Full Scale Intelligence Quotient (FSIQ) of < 70] and functional ability, which has been acquired in childhood.[1–3] In this report, the terms 'intellectual disability' and 'learning disability' are used interchangeably; for the most part, we use the term 'intellectual disability', but we use the term 'learning disability' when referring to services, as this is how services are generally described.

Cognitive–behavioural therapy (CBT) is the treatment of choice for common mental health problems,[4] and widening access to CBT is seen as a major policy priority. For example, in 2007 the UK Department of Health allocated £170M to train 3600 CBT therapists in England through the Increasing Access to Psychological Therapies (IAPT) programme.[5] As in so many other areas, people with intellectual disabilities have higher levels of unmet need but receive less effective treatment, despite the legal requirement to deliver health services in a non-discriminatory manner.[6] IAPT guidance states that 'Commissioners have a duty to ensure that services are equally accessible to people with learning disabilities and will want to ensure that therapists are able to provide the level of care that is required to those with additional needs' and that 'It is important that mental health services and learning disability services work collaboratively to ensure that services are both available and effective for people with learning disabilities'. The guidance goes on to state that 'Some areas have developed local joint protocols but, unfortunately, this type of partnership working still does not happen in many areas'.[7]

There are many barriers that limit access to psychological therapies for people with intellectual disabilities, including social restrictions, communication problems, challenging behaviours, a failure of general practitioners to recognise mental health problems, and exclusion criteria operated by specialist mental health services.[7,8] However, a further problem is that the necessary research on effectiveness of psychological therapies for this population is still at a rudimentary stage. It is only recently that CBT has been adapted for people with intellectual disabilities. There is a relatively large case study literature describing successful outcomes for CBT in a variety of mental disorders,[9–12] but the evidence from controlled trials is sparse. With the exception of two small controlled trials in depression,[13,14] anger is the only psychological presentation in which controlled trials have been used to evaluate CBT interventions for people with intellectual disabilities.

Anger in people with intellectual disabilities

Anger is a frequent problem for many people with intellectual disabilities, and although many individuals are able to manage anger appropriately, it is often expressed as verbal and/or physical aggression.[15,16] Prevalence estimates for problem anger in the general population of people with intellectual disabilities vary between 11% and 27%,[17] and a recent review of studies of aggressive challenging behaviour among people with intellectual disabilities reported that over half of the population display some form of aggression.[15] They are also significantly more likely to be victims of aggression.[18] Aggression resulting from uncontrolled anger can lead to serious consequences, which include exclusion from services, breakdown of residential placements, and involvement with the criminal justice system.[19–21] Aggressive behaviour can also have an impact on the psychological well-being of care staff[22] and the quality of care they provide[23] and on the health and well-being of family carers.[24–26]

Most of the techniques used to address anger in people with intellectual disabilities are based on an approach developed by Novaco *et al.*,[27–29] initially for use in an intellectually able population. The approach is recognisably the same as that used in other externalising disorders; for example, there are close parallels with relapse prevention for substance abuse.[30] Anger management consists of teaching clients to be aware of situations that evoke anger, to be aware of becoming angry, and to develop skills to control and manage anger. The intervention can be delivered in either a group or an individual format. Anger is conceptualised as an emotion with physiological, behavioural and cognitive components, and the programme includes a range of coping skills aimed at each of these areas: physiology (relaxation), behaviour (distraction, time out, walking away, help seeking, use of humour and assertiveness) and cognition (cognitive restructuring, problem-solving). As is clear from this list, there is an emphasis on behavioural coping skills. Relaxation is also prominent, as it is usually introduced very early in the programme and used throughout. Typically, however, cognitive skills are introduced later in the programme.[28–30] For more serious cases, particularly those involving resistance, an anger treatment protocol has been developed. This includes an initial motivational interviewing module, a more elaborate individualised formulation, and a greater emphasis on cognitive restructuring.[16]

Prior to the development of these techniques, challenging behaviour by people with intellectual disabilities had traditionally been managed pharmacologically or behaviourally[31,32] and these methods are still widely used.[33,34] In the first study of a CBT-based anger management intervention, Benson *et al.*[35] compared the effects of relaxation training, self-instructions, problem-solving, and an anger management programme including all three components. They reported that all four interventions were effective in decreasing anger when administered in a group setting.[35–37] Subsequently, a number of Phase II trials have compared variants of Benson's anger management programme with a waiting list control group. The 10 published studies are summarised in *Table 1*.

The studies listed in *Table 1* are fully consistent in reporting that anger management is effective in helping people with intellectual disabilities to manage their anger better, and that treatment gains are maintained over follow-up periods of up to 30 months. They are also fully consistent in reporting that no improvement is shown by participants in the waiting list control group. *Table 2* shows the effect sizes obtained in these studies. All studies, bar two, reported large or very large effect sizes (mean $d = 1.19$); in the two studies in which only a medium-sized effect (<0.8) was reported immediately post treatment,[11,42] the effect of the intervention subsequently increased at longer-term follow-up. Similar effect sizes were found for group ($n = 10$ studies; $d = 1.15$) and individual ($n = 2$ studies; $d = 1.38$) formats, and for self-ratings ($n = 9$ studies; $d = 1.13$) and carer ratings ($n = 3$ studies; $d = 1.38$). Anger ratings decreased by around 17% in the intervention groups, whereas they increased by around 7% in the control groups. Similar results have been reported in a linked series of studies in which a more complex cognitive-behavioural anger treatment protocol was used with people in a forensic setting. The participants in these studies included people with mild intellectual disabilities as well as some more intellectually able people whose FSIQ was in the 'borderline' range.[16,46,47]

In reviewing these studies, a number of methodological issues are apparent:

1. The anger treatment studies were conducted in a forensic setting, and the results may, therefore, not generalise to community settings.
2. Only two studies[39,42] used randomised allocation to groups, and one of these[39] was extremely small.
3. In some studies[11,40] the groups were not well matched at baseline.
4. There was some overlap between groups or samples; for example, in some studies, participants in the control group were later added to the intervention group.
5. The relatively small size of most studies meant that they involved few centres and few therapists, and, where a group format was used, very few groups.
6. Several studies, including some of the largest,[43,44] did not include a long-term follow-up, and with few exceptions[11,16,42] studies that did include long-term follow-up followed up only the intervention group, not the control subjects.

TABLE 1 Studies of anger management vs waiting list control participants[a,b]

Study	Year	*n*:[c] Format	Sessions	Duration (hours)	Rater	Follow-up
Rose *et al.*[38]	2000	25: group	16 × 2 hours	32	Self	12 months
Willner *et al.*[39]	2002	16: group	9 × 2 hours	18	Self/carer	3 months
Lindsay *et al.*[40]	2004	47: group	40 × 1 hour	40	Self/carer	3–30 months
Willner *et al.*[11]	2005	17: group	12 × 2 hours	24	Self/carer	6 months
Rose *et al.*[41]	2005	86: group	16 × 2 hours	32	Self	3–6 months
Hagiliassis *et al.*[42]	2005	29: group	12 × 2 hours	24	Self	4 months
Rose *et al.*[17]	2008	41: individual[d]	16 × 0.75 hour	12	Self	None
Rose *et al.*[43]	2009	64: group and individual[d]	16 × 2 hours 16 × 0.75 hour	32 12	Self	None
Rose[44]	2010	56: group	16 × 2 hours	32	Carer	None
[e]Collado-Castillo[45]	2011	36: group	??	??	Self	None

a The table lists all published studies in which a cognitive–behavioural anger management intervention for people with intellectual disabilities has been compared with a waiting list control group. Anger management refers to programmes that teach a range of anger coping skills, usually in a group setting; the table excludes studies of anger treatment,[16,46,47] which refers to a more complex individual therapy based on stress inoculation.

b This list is based on a literature search conducted in August 2011 (updated February 2012). Four databases (PubMed, Web of Knowledge, EBSCO and PsycINFO) were searched back as far as the publication of the paper by Benson *et al.*,[35] using the following two sets of search terms: (1) (anger or aggression) and [(learning or intellectual) and (disability or disabilities)) or (mental retardation)] and (2) (anger or aggression) and cognitive and (behaviour or behaviour) and therapy. These searches returned between 350 and 900 articles, which were searched by hand for studies that compared a cognitive–behavioural intervention for anger with a control group in adults with intellectual disabilities. Hand searches were also conducted back to 2008 of the following 12 journals: *Advances in Mental Health and Intellectual Disability*, *American Journal on Intellectual Disability*, *British Journal of Developmental Disability*, *Developmental Disability Research Reviews*, *Intellectual and Developmental Disability*, *Journal of Applied Research in Intellectual Disabilities*, *Journal of Autism and Developmental Disability*, *Journal of Developmental and Physical Disabilities*, *Journal of Intellectual and Developmental Disabilities*, *Journal of Intellectual Disability Research*, *Journal of Mental Health Research in Intellectual Disability* and *Research in Developmental Disability*. A repeat of the database search in February 2012 did not identify any additional publications.

c The numbers listed are the total number of participants in the study; they may not have been equally distributed between groups.

d Participants in the study of Rose *et al.*[17,43] received 14–18 sessions of 30–60 minutes' duration. The figures in the table provide a rough average.

e The study of Collado-Castillo[45] is published in abstract only. Positive results were reported for two interventions – cognitive reappraisal and problem-solving – but few further details are available.

7. One study[16] was conducted over a period of > 10 years, during which time the characteristics of the population changed.
8. One study used only third-party (carer) ratings to assess anger.[44] All other studies included first-person reports from service users but only four studies included both of these sources of information.[11,16,39,40]
9. Some of the interventions were manualised;[11,16,42,46,47] most were not.
10. In those studies where the intervention was manualised, no assessment of fidelity to the manual was reported.

Although there is evidence that treatment gains generalise across settings,[48] little is known about which are the crucial components of the intervention. However, one recent study that used a novel assessment instrument, the Profile of Anger Coping Skills (PACS),[11] reported a significant correlation between decreased anger reactivity and increased usage of anger coping skills, thus providing some evidence that the specific psychoeducational content of the anger management curriculum is intrinsic to its effectiveness.[48] There is also some evidence that outcomes are better in more intellectually able

TABLE 2 Effectiveness of anger management vs waiting list control participants[a,b]

					Control		Intervention		Effect size[c]
Study	Year	Format	Rater	Instrument	Mean	SD	Mean	SD	
Rose *et al.*[38]	2000	Group	Self	AI	102.5	10.4	88.5	11.8	1.27
Willner *et al.*[39]	2002	Group	Self	AI/PI	116.4	17.2	86.3	28.8	1.31
			Carer	AI/PI	102.2	15.6	83.7	15.9	1.17
Lindsay *et al.*[40]	2004	Group	Self	DPI	100.0	31.0	69.5	40.6	0.89
Willner *et al.*[11]	2005	Group	Self	PI	111.6	32.2	86.7	40.7	0.68
			Carer	PI	119.5	40.6	55.8	23.8	1.82
Rose *et al.*[41]	2005	Group	Self	AI	103.0	12.7	90.3	11.7	1.06
Hagiliassis *et al.*[42]	2005	Group	Self	NAS	101.4	23.6	120.5	26.3	0.77
Rose *et al.*[17]	2008	Individual	Self	AI	104.2	14.3	86.7	14.9	1.20
Rose *et al.*[43]	2009	Group	Self	AI	104.2	10.0	88.0	11.4	1.52
		Individual	Self	AI	104.2	10.0	85.4	14.0	1.57
Rose[44]	2010	Group	Carer	AI	102.4	9.5	90.3	14.9	0.99

AI, Anger Inventory; PI, Provocation Index: DPI, Dundee Provocation Inventory; NAS, Novaco Anger Scale (an increased score in this study represents a decrease in anger); SD, standard deviation.

[a] Where data were not available in the publication they were obtained from the author. The table includes all of the studies listed in *Table 1*, except for Collado-Castillo,[45] for which the data were not available.

[b] In order to present data on a standardised scale across studies and measures, all data are reported as percentage of the pre-treatment mean.

[c] Effect sizes were calculated as Cohen's *d*: difference of intervention and control group scores post treatment, divided by the mean of the two SDs. Differences in baseline scores were generally very small but one case (carer ratings)[11] intervention group scores were 25% lower than control group scores at baseline. In order to correct for this difference, pre-treatment means were subtracted from post-treatment means before calculating '*d*'.

participants[39,41,42] (although this has been disputed),[49] and in participants who are accompanied to the group by a carer.[39,41]

There is evidence that 'paraprofessionals', working under supervision following minimal training, can deliver effective manualised CBT.[50] In order to capitalise on the potential benefit of carer involvement, some studies have involved carers (day-service staff) to deliver an anger management intervention to people with intellectual disabilities, with positive outcomes.[11,48] A manualised group intervention delivered by day-service staff has also been reported to improve depression in people with intellectual disabilities.[14] There are potential advantages to this approach, because care staff who are recruited as 'lay therapists' become familiar with the anger coping techniques that participants learn and are, therefore, able to provide ongoing support outside the group sessions. They are also able to disseminate information about therapeutic methods and patient progress to other staff. Such joint group working also has the potential to improve relationships, and so decrease conflict, between staff and service users.

Rationale for the trial

Although the literature reviewed in *Table 1* is promising, studies have typically been relatively small, and have not used fully randomised allocation to treatment;[51,52] some further methodological limitations are summarised above. A Cochrane review of interventions for aggressive behaviour in people with intellectual disabilities published in 2008[52] identified only four studies suitable for inclusion, including one study of group-based CBT for anger[39] and one study of individual CBT for anger.[16] The review concluded that:

> *The existing evidence on the efficacy of cognitive behavioural and behavioural interventions on outwardly directed aggression in children and adults with learning disabilities is scant. There is a paucity of methodologically sound clinical trials. Given the impact of such behaviours on the affected individual, his or her carers and on service providers, effective interventions are essential. It is also important to investigate cost efficacy of treatment models against existing treatments. We recommend that randomised controlled trials of sufficient power are carried out using primary outcomes of reduction in outward directed aggression, improvement in quality of life and cost efficacy as measured by standardised scales.*[52]

The present study aimed to address these objectives, using a manualised intervention that was delivered by care staff in the settings that participants attended for their day care.

Fidelity of the intervention

There is evidence that the effectiveness of therapeutic interventions decreases as therapies move from university-based research studies into routine clinical practice. For example, a meta-analysis of multisystemic therapy for adolescent conduct disorder reported that effect sizes achieved in community effectiveness studies were less than one-third of those reported in university-based efficacy studies.[53,54] In some cases, interventions that appear clearly efficacious may be ineffective in a community setting,[55] although equivalent outcomes may also sometimes be reported.[56]

The generally accepted 'technology model' of psychotherapy research[57,58] involves three elements: specification of treatments in manuals, training and supervision of therapists to ensure that treatment is delivered as uniformly as possible, and monitoring of treatment delivery. Therefore, treatment integrity or fidelity checks are needed, in order to be able to monitor the extent to which treatments are delivered appropriately.[59] There is evidence that community therapists who claim to deliver evidence-based interventions may do so to a very limited extent.[60,61] This is despite the fact that the fidelity with which proven interventions are administered is known to be important for maintaining high levels of effectiveness.[62,63] Anger is an area for which the inclusion of fidelity checks is associated with better clinical outcomes in the general population.[64]

Fidelity-monitoring instruments are usually developed for use with individual therapy, and although some of the existing instruments have been adapted for use in a group-based context,[65] they do not take into account the particular social and communication skills that are needed when working with people with intellectual disabilities. In order to monitor treatment fidelity in our randomised controlled trial (RCT), we therefore needed to develop an instrument that would take into account both the group context and the client group. Another feature of the trial was that the intervention was to be delivered by lay therapists (day-service staff). There is evidence that 'paraprofessionals', working under supervision following minimal training, can deliver effective manualised CBT,[50] and this strategy has previously been used to deliver anger[11] and depression[14] interventions to people with intellectual disabilities. The use of lay therapists in our trial made it particularly important to be able to monitor the fidelity of treatment implementation, in order to evaluate the effect of this factor on outcomes.

The scale developed for this purpose in the present study was an adapted version of the Cognitive Therapy Scale for Psychosis (CTS-Psy) developed by Haddock *et al.*[66] to assess the competence of therapists carrying out CBT with people who have psychosis. The scale includes ratings on both structural and process elements of therapy, along with global quality ratings. For example, structural components include setting an agenda and the use of homework tasks, while process elements include an attempt to foster a collaborative relationship and promoting understanding through communicating effectively. The key aims were to ensure that the scale was sensitive to the therapists' ability to apply the therapeutic processes flexibly, and that the approach remained accessible to people with psychosis who had impairments such as an inability to pick up social cues or problems with emotional regulation. This goal of examining the therapists' ability to make CBT accessible to people with psychological impairments is what makes this scale applicable for therapists using CBT with people who have intellectual disabilities. It has already been successfully used to examine the treatment fidelity of psychologists working with people who have intellectual disabilities and a range of emotional difficulties, including anxiety, depression and anger problems.[67] Hence, the published scale[66] was considered an appropriate starting point for the development of a measure to examine the fidelity and competence of therapists implementing group-based CBT interventions for people with intellectual disabilities.

Qualitative research

Whereas the positivist approach,[68] on which the methodology of the quantitative research is based, can capture a detailed picture of psychological state before and after the intervention and can establish whether or not any differences observed are more than due to chance and thus attributable to the intervention, it is less well equipped to address and answer 'why' and 'how' questions and throw light on interpersonal processes and personal experiences. This is the raison d'être of social constructionist methods such as interpretative phenomenological analysis (IPA)[69] and thematic analysis (TA).[70] In order to address the experiences of those delivering, receiving, and hosting the intervention, the current research incorporated a substantial qualitative component. TA is an atheoretical method for identifying, analysing, and reporting patterns (themes) within data, and provides a means of organising information derived from different respondents.[70] IPA aims to understand how a particular individual, in a particular context, makes sense of a particular phenomenon; hence, the two central components of IPA are that it is both phenomenological and interpretive. A phenomenon is a particular experience or a state that an individual experiences, and research that uses IPA is interested in how an individual makes sense of, and the meanings they assign to, particular phenomena. Therefore, the participant is viewed as the expert, with the researcher interpreting and applying psychological theories to participants' first-hand experiences.[69]

Although some authors have argued that positivist and social constructionist approaches cannot be combined within one research project because they are based on radically different and incompatible philosophical underpinnings,[71] many other researchers have accepted a pluralist position that allows quantitative and qualitative methodologies to complement each other as '. . . a strict divide hides more than it illuminates and there is a very strong case for combining both research traditions'.[72] For example, McLeod[73] stated that RCTs that use only quantitative outcome measures may 'privilege some voices and silence others', as the experiences and feelings of the participants are not heard in their own words.

Thus, a qualitative component was added to the current study in order to enhance the trial findings and (1) investigate the personal experiences of service users who participated in the programme, free from the restrictions of prescribed topics, language and evaluations that are inherent to psychometric self-report rating scales; (2) investigate lay therapists' views and experiences of taking part in a CBT group intervention and acting in the role of 'therapist'; and (3) obtain managers' views of the impact of the intervention on the wider service. The inclusion of this component also enables a contextualisation of the quantitative findings, as well as providing important pointers to how such interventions can be rolled out in practice.

Objectives

The main objective of the study was to evaluate the effectiveness, compared with treatment as usual, of a manualised anger management intervention, delivered to people with mild to moderate intellectual disabilities by care staff in a service setting, in reducing levels of reported anger.

Secondary objectives, which address both outcome and process issues, were to explore and evaluate:

1. the effectiveness of the intervention in increasing anger coping skills and reducing levels of aggression
2. the impact of the intervention on mental health and quality of life
3. the extent to which similar results are observed by carers in the home setting as in day services
4. the extent to which intellectual or receptive language ability, initial mental health status, carers' attributions of challenging behaviour, and/or the climate within the group, influence the outcome of the anger management intervention
5. the experience of service users who participate in the programme
6. staff attitudes to and routine experiences of managing anger within services
7. staff experiences of acting in the role of 'therapist' and the perceived impact of the intervention on the wider service
8. the cost consequences of the programme in relation to the utilisation of health and social care services.

Two further methodological objectives were to:

1. develop an instrument for monitoring the fidelity of group-based CBT interventions for people with intellectual disabilities, as described above
2. evaluate a novel self-rating version of the PACS, which previously has been used only as a third-party rating by carers.

Chapter 2 Methods

Design

This was a multicentre Phase III cluster RCT of a manualised anger management group intervention compared with a 'treatment-as-usual' waiting list control group, with randomisation of the group rather than the individual. A power calculation, based on a medium-sized effect ($d = 0.57$), a significance level of $p < 0.05$, 80% power and intracluster correlation coefficient (ICC) = 0.11, indicated a target of 72 participants in each group of the trial.[74] To arrive at this target, we aimed to recruit a single group of four to nine service users (average six) in each of 30 participating centres. This total of 180 participants allowed for 20% loss to follow-up.

Randomisation

Centres were recruited, and baseline data collected on all participating service users and their key workers, before randomisation of the centre took place. Randomisation was performed using the method of minimisation.[75,76] Centres were balanced on (1) their service users' average baseline self-reported Provocation Index (PI) score (see *Primary outcome measure*, below); (2) the number of service users recruited; and (3) the average number of hours per week spent by the service user with at least one trainer outside of sessions. A random component, set at 80%, was used alongside the minimisation procedure to ensure that the process was not completely determined.

Ethical and governance approval

Ethical approval for the trial was granted by the South East Wales Research Ethics Committee (09/WSE03/41). Research and development (R&D) approval was granted in all regions, with additional participation identification centre approval where required.

Changes from the published protocol

There are no major changes from the published protocol[74] (see *Appendix 1*).

Service and participant recruitment

Services and service users

Thirty services providing day activities for people with mild to moderate learning disabilities were recruited, on the basis that they reported significant anger control problems among some of their service users. Services were run by statutory or independent sector providers, and varied in their mode of operation from traditional day centres to individualised community-based activity programmes, including residential care providers. The study was implemented in three regions: one in Wales, one in England and one in Scotland. In each region, 10 services were identified, of which five were randomly allocated to the intervention group and five to the control group. Between four and eight service users were recruited to each group.

Participating centres received funding (£1000) to cover the costs of replacing the staff who acted as 'lay therapists'. In order to maintain engagement in services randomised to the control group, training and supervision to run a group was offered at the end of the controlled comparison phase of the study.

Other participants

For each service user, a key worker and, where applicable, a home carer were also recruited (not all service users had a home carer depending on their residential setting). In each participating centre, between two and four staff were recruited to act as 'lay therapists'. Staff were nominated by their managers and selected, without reference to formal qualifications, on the basis of their motivation to take on this role and their openness to using a cognitive–behavioural approach. Service managers were also recruited from each participating centre.

Inclusion and exclusion criteria

Participating services were required to meet all of the following inclusion criteria and neither of the exclusion criteria (*Box 1*).

Service users were eligible for the trial if they met all of the following inclusion criteria and none of the exclusion criteria (*Box 2*).

Trial procedures

Consent

A contractual agreement was negotiated with participating services. Consent was sought from five types of participants: the service users themselves, their key workers, their home carers, lay therapists and service managers. Written consent was taken from the service managers, lay therapists, key workers and home carers, using consent forms and procedures that complied with standard Research Ethics Committee guidelines.

For service users, a more accessible consent procedure was used:

1. The trial was explained verbally in simple terms, using a standard script written in accessible language, with frequent checks for understanding.
2. In addition to the general information sheet that was provided to all participants, service users were also given a simplified accessible pictorial information sheet to take home and read in their own time and at their own speed, with support from carers.
3. At least 2 days were given to consider and ask questions of researchers or carers.
4. The explanation was repeated in a second meeting.
5. Consent was recorded by the service user, checking and initialling a set of tick boxes and signing the consent form.
6. In order to assure that the service user had been properly informed, without coercion, the whole process was witnessed and signed off by a staff member who was independent of the research team.

For therapists and service users selected for interview after the end of the intervention (see below), a separate consent was taken at the time, using the same procedures as above.

BOX 1 Participating services: inclusion/exclusion criteria

Inclusion criteria

1. Reported anger control problems among at least four service users who met individual inclusion criteria and wanted to participate
2. Availability of at least two staff members willing to be trained as group leaders
3. The service manager would provide written agreement to participate

Exclusion criteria

1. The service was already running an anger management programme similar to this one
2. There were no suitable facilities for group work

BOX 2 Service users: inclusion/exclusion criteria

Inclusion criteria

1. An adult attending a service for people with mild to moderate learning disabilities
2. Identified by service staff as having problems in managing their anger
3. Wishing to learn to improve his or her anger management
4. Able to provide informed consent
5. Able to complete the assessments

Exclusion criteria

1. Attending the service for a reason other than a diagnosed learning disability[a]
2. Currently receiving psychological treatment for anger or aggression
3. Urgently requiring referral to a clinical psychologist for individual treatment of anger or aggression
4. Experiencing circumstances which indicates that a POVA procedure should be initiated
5. If for any other reason the supervising Clinical Psychologist makes a clinical judgement that participation in the group would be counter-indicated

POVA, protection of vulnerable adults.

[a] This does not mean that participants were excluded if they did not have a diagnosed learning disability; it refers rather to individuals with other conditions (e.g. recently acquired brain damage) who may be supported within a learning disability service because it provides the 'best fit', available in their local area, to their needs.

Baseline measures

After a service user had provided written consent, the first assessment administered was the Comprehensive Quality of Life Scale – Intellectual Disability (ComQoL-ID).[77] This instrument assesses quality of life via ratings of the importance of and satisfaction with different life domains. However, these ratings are preceded by a set of exercises to assess the respondent's ability to use simple rating scales and the ability to order quantities using a Likert-type scale. This part of the ComQoL was used to assess the inclusion criterion 'able to complete the assessments'.

For service users who were assessed as eligible, a battery of psychometric and health economic assessments (described below) was administered prior to randomisation. Service users put forward for inclusion who were able to provide consent but unable to complete the assessments were allowed to attend the anger management group but were excluded from the trial.

Participant characteristics

Intellectual and receptive language abilities were also assessed at baseline, using the Wechsler Abbreviated Scale of Intelligence™ (WASI™)[78] and the British Picture Vocabulary Scale (BPVS), third edition,[79] respectively. Adaptive behaviour was assessed using the short form of the Adaptive Behaviour Scale (ABS),[80] which was completed by the service user's key worker or home carer.

Intervention

Participants in services randomised to the intervention group of the trial received a manualised CBT intervention,[48] consisting of 12 weekly psychoeducational group sessions supplemented by 'homework'. The intervention was delivered by day service staff acting as 'lay therapists', under the supervision of one of three clinical psychologists, each of whom was herself supervised by a consultant psychologist. After randomisation and before the start of the intervention, the clinical psychologist provided the lay therapists with three training sessions, delivered over the course of a single day, covering the principles of anger management and use of the therapy manual. The clinical psychologist subsequently provided fortnightly supervision to the lay therapists during the intervention. Staff training followed a training manual developed within the project for this purpose.

Topics addressed over sessions included the triggers that evoke anger, physiological and behavioural components of anger, behavioural and cognitive strategies to avoid the build-up of anger and for coping with anger-provoking situations, and acceptable ways of displaying anger (assertiveness). Presentation relied heavily on brainstorming (e.g. 'What makes us angry?') and role play. After the first session, about one-third of each session was devoted to discussion by facilitators and group members of participants' experiences, focusing primarily on problem-solving around ways in which situations might have been handled differently to produce a better outcome. In addition to simplifying the language used in sessions, wherever possible the use of written materials was avoided in favour of pictorial representations. Towards the end of every session, participants were asked to undertake a homework assignment, which consisted of working with a staff member to complete a functional analysis ('hassle log') of a situation in which they had been angered that week, which was described, analysed and evaluated, using a pictorial workbook. At the end of the intervention, reports were provided on each of the participants and recommendations were made for further input by staff to maintain and increase treatment gains.

Participants in services randomised to the control group of the trial had no therapeutic contact with the research team until the final post-intervention follow-up assessments had been completed, at which point the same training, intervention and supervision procedures were implemented.

Follow-up assessments

Quantitative outcome assessments were administered before randomisation and in a 2-week window beginning 16 weeks after the date the group was randomised, and again in a 4-week window beginning 6 months later (i.e. 10 months after randomisation). The 16-week time point was chosen to allow 2 weeks before the start of the 12-week intervention for staff training, and a further 2 weeks to take account of likely delays due to centre closures or staff absences. The researchers undertaking the outcome assessments did not have any involvement in training or supervision of the therapists, and were in principle blinded to the group allocation of the service, although the group allocation sometimes became apparent during direct interaction with the service user. After the 10-month follow-up assessments were completed, the lay therapists in the control services were trained and the intervention was delivered to the control groups, followed by further assessments in a 2-week window beginning 16 weeks after the training date.

In addition to the quantitative assessments, a sample of service users and lay therapists was interviewed within 2 weeks (service users) or 4 weeks (lay therapists) after the end of the group, and service managers were interviewed at baseline and at the 10-month follow-up (see *Qualitative assessments*, below). Health-economic data, covering the preceding 12-week period, were collected at baseline and at the 10-month follow-up.

Clinical outcome measures

An overview of the quantitative assessments is shown in *Table 3*.

Primary outcome measure

The main outcome measure was the PI as completed by the service user, at the 10-month follow-up. The PI is a direct measure of felt response to defined situations that may provoke anger, which has frequently been used with this service user group.[28,81] It consists of a list of 25 different situations that can evoke anger, each of which is rated on a four-point scale (0–3) for the amount of anger that it would evoke. Scores on this measure have been shown to correlate with staff-reported levels of aggression.[28]

TABLE 3 Overview of quantitative assessments

Instruments	Completed by:		
	Service user	Key worker	Home carer
Participant characteristics			
Wechsler Abbreviated Scale of Intelligence (WASI)	✗		
British Picture Vocabulary Scale (BPVS), third edition	✗		
Adaptive Behaviour Scale, short form (ABS)		✗	✗
Anger/aggression measures			
Provocation Index (PI)	✗	✗	✗
Profile of anger coping skills (PACS)			
Key worker/carer version		✗	✗
Service user version	✗		
Aberrant Behaviour Checklist (ABC)		✗	✗
Modified Overt Aggression Scale (MOAS)		✗	✗
Controllability Beliefs Scale (CBS)		✗	
Mental health measures			
Comprehensive Quality of Life Scale (ComQoL-ID)	✗		
Glasgow Depression Scale-Learning Disabilities GDS (GDS-LD)	✗		
Glasgow Anxiety Scale-Learning Disabilities GAS (GAS-LD)	✗		
Modified Rosenberg Self-Esteem Scale (RSES)	✗		
Resource utilisation measure			
Client Service Receipt Inventory (CSRI)		✗	✗

Secondary outcome measures

Assessment also involved completion of the PI by a key worker.[11,48] For this and other measures, in the event that a service user's key worker was involved in the trial as a lay therapist, then, wherever possible, the measure was completed by another staff member.

The PACS[11,48] was completed by both service user and key worker to assess the development of alternative, more functional coping skills. The PACS first identifies three situations that reliably trigger anger in the individual service user, then asks for ratings of the usage of each of eight coping skills in each of those three situations. The PACS has previously been used only with key workers and carers. For the purposes of the trial, a modified service user version was produced, with two changes: a more detailed description of each coping skill was provided, and a three-point rating scale, rather than a four-point rating scale, was used. For comparability across respondents, PACS scores were expressed as a percentage of the maximum possible score.

The service user version of the PACS also includes a rating (on a three-point scale) of the anger evoked by each situation, which is elicited prior to the ratings of skill use. This represents a form of imaginal provocation test (IPT)[47] and provides a further measure of the proclivity to experience anger. These Profile of Anger Coping Skills – imaginal provocation test (PACS-IPT) ratings differ from the PI in relating to actual, rather than hypothetical, situations.

Mental health was assessed using the Glasgow Depression Scale (GDS) and the Glasgow Anxiety Scale (GAS), which are established measures of depression and anxiety among people with an intellectual disability,[82,83] and an adaptation of the Rosenberg Self-Esteem Scale (RSES) for people with an intellectual disability.[84] Scores of ≥ 13 on the Glasgow scales are indicative of clinical levels of depression or anxiety. Self-reported quality of life was assessed using the ComQoL-ID;[77] the scaling exercises that were administered at the baseline assessment (see *Baseline measures*, above) were omitted from follow-up assessments.

Aggressive challenging behaviour was assessed by key worker report using the Hyperactivity and Irritability domain items of the Aberrant Behaviour Checklist (ABC)[85] and the Modified Overt Aggression Scale (MOAS).[86] In previous work, severe challenging behaviour has been defined by a criterion of either a combined score of > 30 on the Aberrant Behaviour Checklist – Hyperactivity (ABC-H) and Aberrant Behaviour Checklist – Irritability (ABC-I), or > 4 behaviours rated as a severe problem (i.e. at level 3).[87] Key workers' attributions with respect to challenging behaviour were measured by the Controllability Beliefs Scale (CBS).[88]

In order to assess generalisation across settings, the anger, coping skills and aggression measures (PI, PACS, ABC-H, ABC-I, MOAS) were also completed with the service users' home carers.

For all instruments, the total score was pro-rated to take account of missing items (or, in the case of the PI, 'do not know' responses), provided that a minimum of 80% of items were completed (excluding 'do not know' responses).

Reliability of the instruments used

The internal consistency (Cronbach's alpha) and test–retest reliability of the instruments used are summarised in *Table 4*.

For comparison with the published literature, Cronbach's alpha was calculated from the baseline data (all participants) for all measures except the PACS, ComQoL-ID and MOAS, which do not lend themselves to this assessment because they do not involve computation of summated scales.

Process evaluation

An instrument to measure the fidelity of the delivery of group interventions was developed specifically for this trial, based on observation of two sessions in each group in both the intervention and (subsequently) the control arms of the project. In addition, records were maintained of session attendance and the clinical psychologists kept notes of their supervision sessions with lay therapists.

Fidelity monitoring

Monitors

Fidelity monitoring was carried out by pairs of observers who had no other contact with the intervention. A total of 16 observers (15 unique pairs) participated. One of each pair was usually a consultant clinical psychologist and the other was usually a research assistant. For logistical reasons, only one observer was able to attend some of the sessions; these ratings were used in the analysis of trial data but did not contribute to the development of the instrument.

Fidelity checklist

The CTS-Psy[66] consists of nine sections, with six questions in each, and a tenth that elicits an overall rating of the quality of the intervention. For the purposes of this study, the CTS-Psy[66] was modified in two main ways: some of the content was changed to reflect the different format and client group, and the number of items in each section was reduced from six to three to make the task more manageable using live

TABLE 4 Reliability of the instruments used

Instrument	Internal consistency	Test–retest reliability
PI	0.95[81]	0.86[81]
PACS	N/A	0.78[11]
GDS	0.90[83]	0.97[83]
GAS	0.96[82]	0.95[82]
RSES	0.93[89]	0.80[89]
ComQoL-ID	N/A	0.82[77]
ABC-H	0.95[90]	0.98[90]
ABC-I	0.95[90]	0.98[90]
MOAS	N/A	0.93[86]
CBS	0.89[91]	0.87[91]

N/A, not applicable.

observation. The resulting Manualised Group Intervention Checklist (MAGIC) has 10 subsections, with three items in each (*Table 5*). The subsections cover topics concerning fidelity to the manual; the therapist's communication skills and ability to deliver the training sensitively and effectively, including group process issues; and whether or not clients' cognitive and emotional concerns are directly addressed in the course of the session. Each item is scored as 'present', 'absent' or 'not applicable', giving a maximum score of 30. This simple scoring system was adopted to facilitate the observer's task of recording events reliably in real time.

Ratings were made of the therapy team rather than of individual lay therapists. (This was straightforward because almost always one therapist took the lead on each agenda item.) Items were scored as 'present' if a clear example was observed. Monitors recorded the basis for their judgement in a space created for this purpose on the record form. Once an item had been scored as 'present' it could be deleted only in the case of an egregious violation. (For example, if credit had been given for 'materials were used appropriately' it could be deleted if later there was a particularly inappropriate use of materials.)

For the monitoring of intervention group sessions during the trial, the criteria were as agreed by the monitors in an initial training session, and were passed on verbally to monitors who had not been present. For subsequent monitoring of sessions delivered to the control groups, explicit written criteria were provided. In most cases these simply recorded the previous verbally agreed criteria, but for the five items with the lowest inter-rater reliability the criteria were modified to remove ambiguity. It was also specified that there were only seven items for which ratings of 'not applicable' (see items relating to footnote 'a' in *Table 5*) were permissible.

The items in the fidelity checklist were deliberately worded in ways that made no direct reference to anger, so that the checklist would be equally applicable to interventions for other disorders. For the most part, the guidance notes also did not refer directly to anger. For three items, the guidance notes cited anger-related examples, which could be readily replaced if the checklist was used in a different context.

At the end of the session, the monitors also made global ratings on a 10-point scale of fidelity to the manual, group process, and the principles of CBT, as well as a single overall rating. These ratings were impressionistic and not explicitly tied to specific items on the checklist.

TABLE 5 The Manualised Group Intervention Check (MAGIC)

1 Coverage of session plan
1. Set out the agenda for session
2. Agenda was adhered to during the session
3. Good management of time
2 Feedback
1. Asked for feedback from previous session
2. Ensured that group members clearly understood and adhered to the group rules and the purpose of the session
3. Asked for feedback and reactions to session
3 Understanding
1. Conveyed understanding by rephrasing or summarising what group members said
2. Showed sensitivity by adjusting the content or style of their own communication to help members' understanding
3. Welcomed members' requests for clarification[a]
4 Interpersonal effectiveness
1. Communicated warmth, concern and caring
2. In control of the session, communicated clearly without frequent hesitations/repetitions
3. Able to shift appropriately between listening and leading
5 Engaging participants
1. Explained rationale and requirements for the different activities/elements of the session clearly
2. Did not criticise, disapprove or ridicule group members' behaviour
3. Responded to seemingly irrelevant interruptions in an effective yet diplomatic manner[a]
6 Accessibility of presentation
1. Discussions were pitched at a level that was understood by all group members
2. Materials were used appropriately
3. Care was taken to pace the session at a rate that allowed group members to keep up with what was happening
7 Focus on key cognitions
1. Elicited (or responded to) specific thoughts, assumptions, images, memories, beliefs or perceptions
2. Identified cognitions from members' reports of their problems[a]
3. Considered the link between elicited cognitions and affect[a]
8 Focus on key emotions
1. Acknowledged the emotions of the members in the course of the session[a]
2. Attempted to help members manage their emotions in sessions[a]
3. Made the link between the emotions members expressed in sessions and their particular problems[a]
9 Group processes
1. Encouraged a sense of responsibility and mutual respect among group members
2. Promoted interaction between group members and encouraged participation in group activities
3. Promoted an atmosphere of collaboration between therapists and group members
10 Homework
1. Reviewed previous week's homework
2. Encouraged members to complete homework
3. Asked members if they anticipated any problems with homework

Items are scored as present/absent.

[a] These items could also be scored as 'not applicable'.

Procedure

Monitoring was by direct observation. For each group, two monitoring visits were arranged, with the first planned for sessions 3–6 and the second for sessions 7–10, with a minimum interval of 3 weeks between visits. It was explained to the group members that the monitors were there to observe the session but not to participate. During the session, the two monitors sat to the side of the group and independently completed the 30-item fidelity checklist. Subsequently, they compared their recordings and resolved any disagreements by discussion. Both individual and agreed ratings were used in different aspects of the data analysis.

Qualitative assessments

Interviews were conducted with service users, lay therapists and service managers. Service user and lay therapist interviews were conducted face to face; managers were interviewed by telephone. All interviews were recorded using Olympus digital voice recorders [Olympus™ WS-450S (Digital Voice Recorder), Olympus UK, Southend-on-Sea, a subsidiary of Olympus Corporation, Tokyo, Japan] and Retell telephone recording connections (Retell™, telephone handset recording connector for cassette/MP3/Digital Device – the 156, Retell, Sunbury-on-Thames, UK), and the recordings were transcribed verbatim. Between four and 12 participants are recommended for analysis by IPA as the data need to be rich in detail yet not too unwieldy for the researchers. We interviewed 11 service users, nine lay therapists and eight managers, which we considered sufficient to achieve this ‘richness’.

Service users

We aimed to interview 8–12 service users after the intervention to gain an understanding of their experiences of participating in CBT. Interviews were conducted within 2 weeks of the end of the group by the clinical psychologist from the local region, who had previously met the service user when taking consent but had not attended any of the group sessions. Service users were randomly selected from a ‘short list’ of those participants in each group who were considered to have sufficient expressive language ability to be interviewed and to be willing and able to talk about their experiences of participation. The interviews were conducted according to a semistructured interview schedule, containing questions that encouraged the participants to focus on ‘personal meaning’ and make sense of their experience of the therapeutic process. Participants were asked about their involvement in the group (including their expectations and the perceived value of the group) and the impact of the intervention on them. The interview was designed to cater for potential cognitive deficits, such as limited language comprehension and expression, and short attention span. Visual prompts of group activities (taken from the intervention manual) and of people and places were used during the interview for the interviewer and participant to consult.

Lay therapists

We aimed to interview 8–12 lay therapists post intervention in order to investigate their personal experiences of learning and applying new therapeutic skills as cognitive–behavioural therapists, as well as their impressions of the ‘climate’ within the group and the impact of the group on the wider service. They were selected purposively as those who had been most active in terms of running each group. Semistructured interviews were conducted, within 4 weeks of the end of the group, by a clinical psychologist from outside the region who had not had previous involvement with that group. The interviewees were asked to talk freely about their initial hopes and fears training and working with the manual and the CBT model, the role of ‘therapist’ and support needs in running the group, perceived impact of the intervention, and future developments.

Service managers

A related but separate part of the qualitative evaluation aimed to gain an understanding of service policies and practices for service users who express anger inappropriately, and the effects on services as a whole of hosting a CBT group intervention. This was accomplished by interviewing the managers of the services in the intervention group at the start of the study (before any input to the service), and at the 10-month follow-up. These were structured telephone interviews conducted by a clinical psychologist from outside the region.

Clinical psychologists

At the end of the study, but before having access to any of the group-level data, the clinical psychologists were each asked to predict which of the groups that they had supervised (in both the intervention and control arms) would have the three best and three worst clinical outcomes. (By exclusion, there was also a third set of predicted intermediate groups.) From these predictions, the psychologists were asked to reflect on their experience of supervision and provide the basis for their predictions.

Feedback to participants

After completing the data collection and analysis, the findings were fed back to the research participants and significant others in their lives. The aim was to find out whether or not these individuals considered the results to be credible.[92] This was part of the effort to ensure that the qualitative research was carried out to a high standard and with rigour.

Health-economic evaluation

The economic analysis was in the form of a cost and consequences analysis. Incremental costs of delivering the intervention and its impact on subsequent health and social care resource use were included.

Intervention costs

All resources used in delivering the intervention were recorded prospectively. These included:

1. the time input of:
    i. the consultant psychologist in each region who trained and supervised the clinical psychologists who in turn trained and supervised the lay therapists
    ii. the clinical psychologists in each region who trained and supervised the lay therapists running the groups
    iii. the lay therapists who ran the groups
    iv. administrative/secretarial staff attributable to the intervention
2. travel
3. the costs of other consumables attributable to the intervention (e.g. production of manuals, telephone calls, photocopying and materials used in group sessions).

Resource use was recorded on logs developed for the study. Three logs, one for each category of staff, recorded the time input and related travel costs of each consultant psychologist, clinical psychologist and lay therapist week by week during the intervention period. A fourth log recorded administrative time input, length of telephone calls, numbers of photocopies and the costs of other consumables used, again on a weekly basis. A fifth log was used to record details of each group treatment session, again on a weekly basis. This log included specification of the number of service users attending the session, for how many the session was additional to treatment as usual, the number of lay therapists running the session and its length.

Impact on service use

Information on health and social care resource was collected from service users' key workers and/or home carers for a 12-week period immediately preceding the baseline and follow-up data collections.

Total resource use by each participant was measured using the Client Service Receipt Inventory (CSRI).[93,94] The CSRI is a validated tool that has been previously used in evaluations involving service users with intellectual disabilities.[87,95,96] It is amended for each study to record relevant resource inputs. The CSRI for this study collected data on:

1. accommodation arrangements
2. employment and income
3. use of day services (e.g. attendance at day centres, sheltered work, adult education, etc.)
4. use of psychotropic medication for the control of aggression or related challenging behaviour
5. number and length of multidisciplinary meetings held to discuss their care and the staff and professionals attending each
6. receipt of other community-based professional services
7. receipt of hospital-based services
8. provision of domiciliary support or respite care for participants living independently, in the family home or in minimally staffed residential arrangements
9. staffing levels for participants living in partially to fully staffed residential arrangements
10. hours per week at work lost to informal carers due to the need to provide support because of the participant's anger or aggression.

In order to attribute staffing costs in group residential services to individual participants, the CSRI also recorded:

1. the number of people living in the residential setting
2. typical numbers of staff in the morning, afternoon, evening and night
3. whether night staff were waking, sleeping in or on call
4. whether the participant in question required a similar staff input to other residents and, if not,
5. how much more or less.

Data analysis

Quantitative outcomes

Baseline data

The baseline data were analysed to gain some insight into the basis that different respondents were using to rate the service user's anger (PI) and coping (PACS). The analysis was in two stages. First, bivariate correlations (Pearson or Spearman, depending on the distribution of the data) were computed for all variables. Then six hierarchical linear regression analyses were conducted to predict service user, key worker and home carer PI and PACS scores. Variables were entered in three blocks: demographic variables, mental health measures and challenging behaviour measures. For service users the first block included age, gender and intelligence quotient (IQ); for key workers and home carers the respondent's age was also included. The second block included the service users' ratings on the three mental health measures: GDS, GAS and RSES. The third block included the three challenging behaviour measures: ABC-H, ABC-I and MOAS. Key worker ratings were used for the service user and key worker analyses and home carer ratings were used for the home carer ratings.

Trial outcomes

The primary analysis was based on the intention-to-treat principle and compared the mean self-reported PI between the two groups using a two-level linear regression model, to allow for clustering within centres, with participants at level 1 and centres at level 2, and with baseline levels of the PI as a covariate. Secondary outcomes were analysed similarly, with those that were not normally distributed transformed prior to analysis. This achieved a normal distribution for all data other than the MOAS home carer 10-month ratings, which were analysed by a ranked analysis of covariance.[97] With two exceptions, a square root transformation was used; a square transformation was used for the ComQoL-ID and RSES 10-month data.

Formal subgroup analysis of those who were above a threshold self-reported PI of 25 (i.e. a mean item score of 1.0) at baseline, and those who met formal criteria for a diagnosis of 'learning disability', was undertaken through the fitting of interaction terms to the primary model. Other exploratory analysis assessed whether or not the effect of the intervention differed in different service settings (local authority/non-local authority) and by intellectual and language ability.

The intention-to-treat analysis conflates two effects: the efficacy of the intervention (in participants who receive it in full) and its effectiveness in a community context (where some participants may receive the intervention in an attenuated form, or not at all). Standard methods for investigating the former (e.g. per-protocol and on-treatment analysis) are prone to biases induced by not preserving randomisation. Therefore, a complier-adjusted causal effect (CACE) was estimated, which estimates outcomes for participants who complied with the intervention and compares them with the outcomes of would-be compliant participants in the control group.[98,99] An instrumental variable regression analysis was used to estimate the CACE for each outcome measure. For the purposes of these analyses, a complier was taken as someone who had attended at least 8 of the 12 sessions.[64] As this is a cluster randomised trial, the clustering of compliance, as well as outcome data, was also considered by calculating ICCs for both compliance states and compliance itself.[100]

A post hoc analysis of PACS-IPT scores was conducted using a ranked analysis of covariance, based on the median anger rating of each participant across the three PACS scenarios. The PACS-IPT table in *Chapter 6* (see *Table 43*) gives the percentage in each median category at each of the three time points, with *p*-values for the two-ranked analysis of covariance (ANCOVA) models (16 weeks and 10 months – both post randomisation and controlled for baseline).

Pre–post study

As the control groups received the intervention following the 10-month follow-up assessments, all centres provided pre-intervention and 16-week (post-intervention) follow-up data. These pre–post data were analysed to identify factors predictive of immediate post-treatment outcomes.

Data were analysed by fitting hierarchical two-level (service user or key worker responses nested within day services) linear regression models (the PACS-IPT outcome was analysed by fitting a linear regression model to the ranked data), based on all cases for which complete data were available. Some of the significant predictors identified in the models were explored by adding interaction terms. Five blocks of variables were included in these analyses, which were introduced into the model sequentially:

1. service user demographics, as well as the baseline value of the dependent variable
2. service user demographics
3. service user mental health
4. lay therapist characteristics
5. centre characteristics
6. implementation characteristics.

The variables included within each block are listed in *Table 6*.

Three variables were included in all models: the baseline score of the dependent variable and the service user's age and gender. Otherwise, the selection of variables within each block to include in the final model was determined using the Akaike information criterion (AIC) as follows:

1. all variables were entered singly; the variable causing the largest drop in AIC was retained
2. all remaining variables were entered singly; the variable causing the largest drop in AIC was retained
3. other variables were entered singly, and those causing a drop in AIC were retained.

TABLE 6 Variables entered into hierarchical linear regression analyses of the pre–post data

Block 1: Service user demographics
Age
Gender
FSIQ
Receptive language ability
Block 2: Service user baseline mental health
Depression
Anxiety
Self-esteem
Quality of life
Control over challenging behaviour
Block 3: Lay therapist characteristics[a]
Age
Gender
Years working in intellectual disability services
Highest qualification
Block 4: Centre characteristics
Type of centre
Region
No. of participants in the group
Block 5: Implementation characteristics
No. of sessions attended
Fidelity of delivery

[a] Lay therapist characteristics refer to the lay therapist who was identified as taking the lead in each group.

Two of the variables in block 4, region and centre type, were partially overlapping, as most of the non-local authority centres were located within the same region. In cases in which the above algorithm indicated that both of these variables should be retained, the variable causing the larger drop in AIC was retained in the final model.

Further details of the pre–post analysis are provided in *Chapter 9*.

Process evaluation

Fidelity of the intervention

The number of sessions received by each intervention treatment group, the mean number of service users and lay therapists present per session and the mean length of session were calculated from the information collected to cost the intervention (see *Intervention costs*, above).

Inter-rater reliability, for individual items and groups of items in the MAGIC, was calculated as percentage agreement and Cohen's kappa. For the global scores, agreement was assessed by calculating intraclass correlation coefficients.[101] Reliability was considered inadequate when the interobserver agreement was

< 75% and Cohen's kappa was < 0.65. A principal components analysis, using varimax rotation with Kaiser normalisation, was conducted on the MAGIC items.

Further details of the fidelity analysis are provided in *Chapter 5*.

Qualitative outcomes: service users and lay therapists

Because service user and lay therapist interviews encouraged the participants to focus on 'personal meaning' and making sense of their experiences of the therapeutic process, IPA[102] was used to understand the interviewees' first-hand experiences of participating in or facilitating the group and to interpret these experiences. The data analysis followed standard IPA methodology. The first stage of the analysis involved reading and re-reading the transcripts, and making notes of any observations in the data. More detailed line-by-line coding was then used with the codes being consistent with the participants' own words. From the line-by-line coding, a number of themes were identified, which were more interpretive. Finally, all of the themes were listed and relationships between the themes identified and clustered together to create superordinate themes. Themes were excluded if they did not fit in the emerging data or were not supported by 'rich' data.

Findings from qualitative studies are rarely replicable. However, results in one area of research can be useful in influencing other similar areas.[103] Triangulation was used throughout the analysis to ensure that the results were valid. This involved discussing the analysis of three service user and three lay therapist transcripts between two of the researchers to ensure that the themes linked to the participants' own words. Good agreement was found. One of the researchers then completed the analysis.

Qualitative outcomes: service managers

As the focus of the service manager demanded a structured, factual line of enquiry, TA[104] was used to categorise participants' responses into themes and subthemes. The responses to each topic raised by the interviewers were grouped together on the basis of similarities. The concepts expressed were then summarised. This resulted in a number of initial themes, which were then collapsed into wider themes. It was thereby possible to identify commonalities and diversity with regard to reported expectations, views and attitudes of carers/professionals.

Care was taken to ensure that the content of the emerging themes was grounded in the original data. An audit of the initial three interviews was carried out in the form of independent analysis of the transcripts by two researchers, who then compared and discussed in detail their emerging themes. Good agreement was found. One researcher then completed the analysis.

Clinical psychologists' predictions

The relationship between clinical psychologists' predictions and clinical outcomes was tested quantitatively, using non-parametric (Kruskal–Wallis) analysis of variance of the effect of predicted set membership on fidelity, and two-level (participant within centre) ANCOVA (controlling for pre-intervention scores) of the effect of predicted set membership on service user and key worker PI and PACS scores. As these predictions concerned both sets of interventions (intervention and control arms), the relevant outcomes were those recorded at the 16-week follow-up. The clinical psychologists' reflections on the basis of their predictions were summarised and reported as a narrative.

Health economic outcomes

Resources used were valued using unit costs for the financial year 2010–11 from a variety of sources specified in *Appendix 2*. Costs are expressed per participant week.

Intervention costs

Staff costs were based on the mid-point salary for the relevant grade of staff uplifted for employers' on costs. Input from the consultant psychologists, clinical psychologists, administrative staff, related travel and consumables could not be attributed to intervention groups run in separate centres but could be calculated for all groups run in separate regions (i.e. Scotland, England and Wales). For each intervention group, unit costs for lay therapist time in preparing for and running the intervention were based on the mid-point salary for the grades of staff who ran the groups, uplifted for employers' on-costs, combined to an overall mean based on information on the relative balance of the grades of staff involved. The total cost of lay therapist input was calculated for each intervention group, together with any related travel costs.

The central costs in each region attributable to psychology input and administrative support were divided evenly between the intervention groups run in each region and added to the total cost of lay therapist input and travel. A cost per service-user hour for each treatment group was then derived by dividing each total by the number of service user hours across the 12 group sessions. These were then averaged to derive an overall intervention cost per service-user hour.

The incremental cost of delivering the intervention was then calculated by deducting an estimate of the direct care cost per hour of local authority day care (treatment as usual), taking account of the ratio of the number of service users for which the intervention replaced treatment as usual to the total number of service users treated.

Impact on service use

For each type of day service, the average cost per week was calculated by multiplying the number of hours per week that the participant used the service by the unit cost per hour for that service and multiplying the result by the number of weeks in the previous 12 that they had received it, divided by 12. Similar calculations were conducted for receipt of community-based services, hospital-based services, domiciliary support and respite care, with, in some cases, the calculation being based on number of attendances or overnight stays rather than hours of resource use.

Average weekly costs of multidisciplinary meetings were calculated by summing the cost of attendance for each staff member or professional present (i.e. unit cost per hour × length of meeting) for all meetings in the previous 12 weeks and dividing by 12.

The costs of staffing for people living in staffed residential arrangements were calculated as follows. The numbers of staff stated to be typically on duty during the morning, afternoon, evening and night were combined to derive the total number of staff hours required per week. The share of staff input attributable to the participant was then calculated to take account of the number of people living in the residential arrangement and the staff's estimate of whether the person in question required more, less or a similar share of staff to other residents. An illustrative calculation is provided in *Appendix 3*.

Unit costs for non-staff-related elements of residential care (i.e. annuitised capital costs, costs of food, heating and lighting, management costs and agency overheads) taken from Curtis[105] were added, appropriate to the nature of the residential setting (hospital/campus facility, fully-staffed group home or semi-independent living).

The costs of psychotropic medication for the control of aggression or related challenging behaviour were calculated using cost information from the *British National Formulary* (BNF) applied to information on medication taken (see *Appendix 4*), dosage, frequency per day and number of weeks during the previous 12 during which the medication had been taken.

Time off work among informal carers was reported only by one respondent, and employment among participants was extremely limited. Accordingly, these were excluded from the analysis which now includes only health and social care resource use.

There were a small number of missing data. Where the datum missing related to an element of service use (e.g. type of agency providing the service, the length of a meeting, the frequency of drug administration per day) but other necessary data to calculate costs were present, the median for the item in question from among those who received that service was imputed and the cost of that service use was then calculated by applying unit costs in the usual way. Where missing data were more general (e.g. it was known that the person lived in the family home and received domiciliary support but the support received was not specified, or that the person lived in a staffed group home but no data on staffing were available), the mean cost of that service element from among those who received a similar service was imputed.

A total weekly service package cost per participant was calculated by summing the above elements. Differences in the costs of health and social care service use between the intervention and control groups at the 10-month follow-up, taking account of baseline levels, were explored using ANCOVA. In the first instance, a two-level (service users nested within services) ANCOVA analysis was performed. However, no clustering at the service level was detected. Therefore, a single-level ANCOVA model was fitted.

As the cost data were skewed, 95% confidence intervals (CIs) were calculated using non-parametric bootstrapping.[106] This produces a CI for the difference between means, which is judged to be statistically significant if the CI does not contain zero. A total of 5000 replications were performed using Stata version 10 (StataCorp LP, College Station, TX, USA) with the cluster command used to account for any correlation at service level (i.e. samples drawn during each replication were bootstrap samples of services). The random seed number was set (at 5) in order to replicate results.

Chapter 3 Participants and settings

Recruitment

Thirty centres were recruited between December 2009 and September 2010, and service users between February 2010 and September 2010. The main intervention started in April 2010 and ended in February 2011. Delivery of the intervention to the control groups started in April 2011 and ended in January 2012.

Settings

Just over half of the services recruited to the trial were local authority day services (17/30), with all but one of the remainder (a NHS residential service) in the independent sector. As shown in *Table 7*, the settings for the trial varied across regions, with a higher proportion of residential services that provided their own day activities in England (including three secure services) than in Scotland or Wales, but settings were well balanced across the intervention and control arms of the trial.

The two arms of the trial were well matched on the variables on which they were balanced at randomisation: their service users' average baseline self-reported PI score, the number of service users recruited, and the average time spent by the service user with at least one trainer outside of sessions (*Table 8*).

TABLE 7 Types of services

	Local authority			Independent: day			Independent/NHS: residential		
Region	Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total
England	0	1	1	0	1	1	5	3	8
Scotland	5	4	9	0	1	1	0	0	0
Wales	4	3	7	1	2	3	0	0	0
Total	*9*	*8*	*17*	*1*	*4*	*5*	*5*	*3*	*8*

TABLE 8 Matching of trial arms on balancing/minimisation variables

Balancing/minimisation variable	Control	Intervention
n	90	91
Baseline self-reported PI score[a]	43.9 (6.3)	43.4 (9.8)
No. of service users recruited[a]	6.0 (5.7)	6.0 (5.7)
Time (hour/week) spent by the service user with at least one trainer outside of sessions[b]	6.7 (3.0 to 8.6)	7.8 (4.7 to 17.0)

a Mean (standard deviation).
b Median (interquartile range).

Participant flow

A summary of recruitment to the study and retention is shown in *Table 9*, with a full Consolidated Standards of Reporting Trials (CONSORT) diagram in *Figure 1*. A total of 212 service users were recruited (against a target of 180), of whom 30 were deemed ineligible because they were unable to complete the assessments and one was withdrawn as he or she no longer wanted to participate. A further two service users were withdrawn prior to randomisation. One service in the intervention arm withdrew shortly after randomisation, which, along with further individual withdrawals from both the intervention and control groups, led to a 9% withdrawal rate overall at the 16-week follow-up. A further 10% of service users withdrew over the next 6 months (including one centre in the control arm), giving an overall retention rate at the 10-month follow-up of 81% (against a projected 80%[74]), with the same number of withdrawals ($n = 17$) in the intervention and control conditions.

After the 10-month assessments, the intervention was delivered to the control groups, with a further 16-week follow-up assessment. The attrition rate over this period was 24%, relative to the starting population, including the loss of two centres; 50 of the original 90 service users in the control group were retained through to the end of the study.

Recruitment and retention rates for key workers were slightly higher than those reported for service users (see *Table 9* and *Figure 1*) because there were a few instances where key workers provided data, with the service user's consent, after a service user had withdrawn from the trial. Here and elsewhere the numbers given for key workers refer to their reports on service users: the head-count was lower because some key workers reported on more than one service user. Home carers were recruited for 71% of the service users, with a higher proportion in the control group than the intervention group. Attrition was higher in this group, with 18% withdrawals at the first follow-up and a further 14% at the second.

Demographics

Service users

Participants' demographic characteristics are shown in *Tables 10* and *11*. As in previous studies of this kind, participants were mainly middle-aged (median age = 38 years) and male (71%), with a median FSIQ of 57. In terms of adaptive behaviour, the mean short-ABS score of 86 converts to a full ABS score of 223, which is equivalent to the 75th percentile of people with intellectual disabilities living in residential or community care.[80] The majority of participants lived in the family home (41%) or in staffed/supported living arrangements (38%). The two groups were well matched on all demographic variables (see *Table 10*).

TABLE 9 Recruitment and retention of participants

	Services			Service users			Key workers			Home carers		
Time point	Cont.	Int.	Total	Cont.	Int.	Total	Cont.	Int.	Total	Cont.	Int.	Total
Baseline	15	15	30	90	91	181	90	91	181	71	56	127
Randomised	15	15	30	89	90	179	89	90	179	71	56	127
16-week follow-up	15	14	29	85	78	163	87	79	166	59	45	104
10-month follow-up	14	14	28	72	73	145	73	77	150	49	37	86
Second 16-week follow-up	12	–	–	50	–	–	51	–	–	19	–	–

Cont., control; int., intervention.

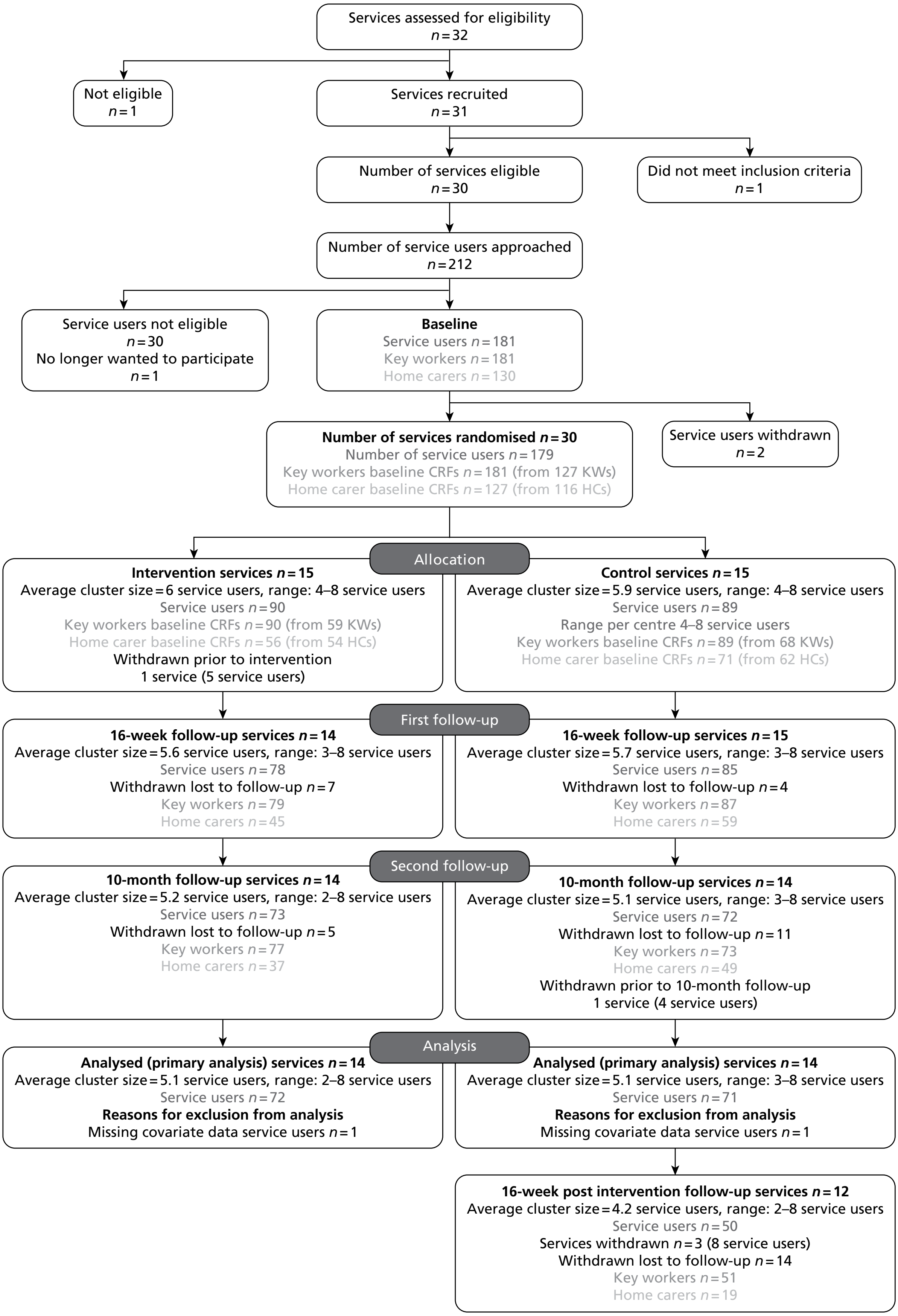


FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) participant flow diagram. CRF, case report form; HC, home carer; KW, key worker.

TABLE 10 Service user baseline demographics by trial arm

Demographic variables	Control	Intervention	Total
n	90	91	181
Age (years)[a]	38.5 (28.0 to 46.0)	37.0 (27.5 to 48.5)	38.0 (28.0 to 47.0)
Gender, % M (proportion)	70.0 (63/90)	71.4 (65/91)	70.7 (128/181)
Accommodation			
Family home	41.2 (35/85)	41.7 (35/84)	41.4 (70/169)
Staffed group home/supported living	37.6 (32/85)	38.1 (32/84)	37.9 (64/169)
Independent housing	5.9 (5/85)	11.9 (10/84)	8.9 (15/169)
NHS or independent sector hospital	8.2 (7/85)	6.0 (5/84)	7.1 (12/169)
Other	7.1 (6/85)	2.4 (2/84)	4.7 (8/169)
Indicators of level of intellectual disability			
FSIQ	55.0 (53.0 to 59.0)	59.0 (55.0 to 64.0)	57.0 (53.0 to 62.0)
BPVS raw score	96.0 (29.78)	107.3 (31.38)	101.7 (31.02)
Total ABS score[b]	84.9 (15.78)	84.5 (15.34)	84.7 (15.51)

a Median (interquartile range).
b Mean (standard deviation).

TABLE 11 Service user baseline demographics by region

Demographic variables	England	Scotland	Wales
n	60	65	56
Age (years)[a]	38.5 (28.0 to 46.0)	41.0 (32.0 to 49.0)	31.5 (24.5 to 42.0)
Gender, % M (proportion)	76.7 (46/60)	64.6 (42/65)	71.4 (40/56)
Accommodation			
Family home	11.7 (7/60)	61.4 (35/57)	53.8 (28/52)
Staffed group home/supported living	60.0 (36/60)	19.3 (11/57)	32.7 (17/52)
Independent housing	8.3 (5/60)	12.3 (7/57)	5.8 (3/52)
NHS or independent sector hospital	20.0 (12/60)	0.0 (0/57)	0.0 (0/52)
Other	0.0 (0/60)	7.0 (4/57)	7.7 (4/52)
Indicators of level of intellectual disability			
FSIQ	56.0 (53.0 to 62.0)	56.0 (53.0 to 62.0)	58.0 (55.0 to 61.5)
BPVS raw score	101.5 (29.92)	96.5 (33.09)	108.1 (29.06)
Total ABS score[b]	90.3 (12.94)	80.7 (15.63)	82.5 (16.60)

a Median (interquartile range).
b Mean (standard deviation).

Participants in the three regions of the trial were well matched on age, gender and indicators of level of intellectual disability (*Table 11*). However, they differed markedly in their accommodation arrangements. In Scotland and Wales, participants lived predominantly in the family home (61% and 54%, respectively). However, in England only 12% of participants lived with families, with 60% in group homes or other supported living arrangements, and 20% in secure (hospital) settings. This reflects the fact that traditional local authority day services still exist in Scotland and Wales, but have been disbanded in many parts of England, leading to recruitment, in this trial group, of residential services that provided their own day activities (see *Table 7*).

Other participants

The median age of key workers (*Table 12*) was 46 years and they were predominantly female (61%). Unlike other references to key workers elsewhere in this report, *Table 12* refers to the head count rather than the number of reports the key workers provided. It describes the 124 key workers recruited for the baseline assessment. During the course of the study a further 37 key workers were recruited as replacements following staffing changes. Their demographic characteristics were similar to those of the original cohort.

The *n*s in this table refer to the actual numbers of key workers. Elsewhere, key worker numbers refer to their reports on service users, which are higher because some key workers reported on more than one service user.

Home carers (*Table 13*) were of a similar age (median = 50 years) and gender balance (65% female) to key workers. Family carers were somewhat under-represented relative to staff carers; excluding service users who lived independently, 45% of service users lived in the family home, but only 37% of home carers were family members (see *Table 13*). This difference reflected the experience that family carers were more difficult to recruit than staff carers. Service users in the intervention group were more likely to have a female home carer but the groups were otherwise very well matched.

Lay therapists (*Table 14*) had a median age of 42 years and 63% were female. They had worked with people with learning disabilities for a median of 9 years, with 6 years in their current organisation and 5 years in their current role. Just over 40% had been educated to higher school-leaving level [National

TABLE 12 Key worker baseline demographics

Demographic variables	Control	Intervention	Total
n	67	57	124
Age (years)[a]	46 (41 to 50)	47 (40 to 55)	46 (40 to 52)
Gender, % M (proportion)	34 (23/67)	44 (25/57)	39 (48/124)

a Median (interquartile range).

TABLE 13 Home carer baseline demographics

Demographic variables	Control	Intervention	Total
n	71	56	127
Age (years)[a]	53 (31 to 58)	49 (36 to 59)	50 (34 to 58)
Gender, % M (proportion)	44 (31/71)	25 (14/56)	35 (45/127)
Family setting[b]	35.7 (25/70)	39.3 (22/56)	37.3 (47/126)

a Median (interquartile range).
b Percentage (proportion) of family vs staff carers.

TABLE 14 Lay therapist characteristics

Characteristics	Control	Intervention	Total
n	45	37	82
Age (years)[a]	42 (11)	43 (11)	42 (11)
Gender, % M (proportion)	27 (12/45)	49 (18/37)	37 (30/82)
Length of time (years) employed to work with people with learning disabilities[b]	6.7 (4.6 to 12.8)	10.0 (6.0 to 17.5)	9.3 (5.0 to 16.0)
Length of time (years) at organisation[b]	5.6 (3.0 to 10.0)	6.3 (4.1 to 9.9)	6.0 (3.4 to 10.0)
Length of time (years) in current role[b]	5.0 (2.0 to 8.0)	6.0 (2.2 to 8.8)	5.4 (2.1 to 8.6)
Highest qualification[c]			
No qualification or NVQ/SVQ level 1	13 (6/45)	8 (3/37)	11 (9/82)
NVQ/SVQ level 2 or GCSEs	9 (4/45)	5 (2/37)	7 (6/82)
NVQ/SVQ level 3, Highers/A-levels or HNC	44 (20/45)	38 (14/37)	42 (34/82)
NVQ/SVQ level 4, HND or irrelevant degree	22 (10/45)	16 (6/37)	20 (16/82)
Relevant degree or professional qualification	11 (5/45)	32 (12/37)	21 (17/82)

a Mean (standard deviation).
b Median (interquartile range).
c Percentage (proportion).

Vocational Qualification (NVQ) level 3, A-level or similar qualifications], a similar proportion had some university or equivalent-level education, and 18% of lay therapists had low [NVQ level 2, General Certificate of Secondary Education (GCSE) or similar] or no qualifications. The lay therapists in the intervention group were more likely to be male (49% vs 27%), and were better educated (32% vs 11% had a relevant degree or professional qualification). However, these differences do not influence the outcome of the RCT, because the lay therapists in the control group occupied this role only after the end of the trial. None of the lay therapists had received any prior formal training in CBT.

Service managers (*Table 15*) were similar in age to the other two groups of staff (median = 46 years), with an approximately equal gender split (46% female). They were comparable with the lay therapists in their occupational history, and all had served in their present role for at least a year. Over three-quarters (77%) had NVQ level 4 or university-level qualifications, and almost half (46%) had a relevant degree or professional qualification. Managers in the intervention group tended to have been with their organisation for longer than managers in the control group, but the two groups were similar in all other respects, including their experience in the management role.

Clinical status at baseline

Reliability statistics (Cronbach's alpha) of the measures for which these could be calculated are shown in *Table 16*. All of the measures showed a high level of reliability ($\alpha > 0.79$), with the exception of the RSES ($\alpha = 0.64$). Service users, key workers and home carers all responded consistently on the PI ($\alpha > 0.89$). This is of particular interest, as this measure has previously been reported only for service users.

Tables 17 and *18* show baseline scores on all clinical variables, as rated by service users, key workers and home carers. Differences between the intervention and control groups have not been analysed statistically,[107] but it is clear from inspection that there was very close agreement between the two sets of scores in all measures.

TABLE 15 Service manager characteristics

Characteristics	Control	Intervention	Total
n	12	14	26
Age (years)[a]	44 (9)	48 (6)	46 (7)
Gender, % M (proportion)	60 (6/10)	50 (7/14)	54 (13/24)
Length of time (years) employed to manage services for people with learning disabilities[b]	6.7 (3.0 to 9.5)	8.4 (5.0 to 14.1)	7.5 (3.5 to 11.2)
Length of time (years) at organisation[b]	4.0 (2.4 to 9.7)	18.3 (5.6 to 25.0)	9.7 (2.8 to 19.2)
Length of time (years) in current role[b]	3.0 (1.1 to 5.7)	4.5 (1.9 to 5.0)	3.8 (1.7 to 5.4)
Highest qualification[c]			
No qualification or NVQ/SVQ level 1	8 (1/12)	7 (1/14)	8 (2/26)
NVQ/SVQ level 3, Highers/A-levels or HNC	25 (3/12)	7 (1/14)	15 (4/26)
NVQ/SVQ level 4, HND or irrelevant degree	25 (3/12)	36 (5/14)	31 (8/26)
Relevant degree or professional qualification	42 (5/12)	50 (7/14)	46 (12/26)

[a] Mean (standard deviation).
[b] Median (interquartile range).
[c] Percentage (proportion).

TABLE 16 Internal consistency of baseline responses

	Service users		Key workers		Home carers		
Measure	*n*	α	*n*	α	*n*	α	Published data
PI	181	0.92	181	0.90	127	0.90	0.95[81]
GDS	175	0.84					0.90[83]
GAS	176	0.88					0.96[82]
RSES	172	0.64					0.93[89]
ABC-H			180	0.90	127	0.91	0.95[77]
ABC-I			180	0.89	127	0.90	0.95[77]
CBS			181	0.79			0.89[91]

Anger

Provocation Index scores were similar to those observed in earlier studies on a comparable population,[11,48] with service users rating themselves higher than they were rated by their key workers or home carers [$F(2,487) = 38.05$; $p < 0.001$]. Key worker and home carer PACS scores were also similar to those reported previously.[11,48] The service user PACS was developed for the purpose of the present study and has not been previously reported. Service users rated themselves as coping better than did their carers [$F(2,475) = 61.3$; $p < 0.001$].

Mental health

A relatively high proportion of service users displayed significant levels of depression, with 34% of them scoring at or above the cut-off value for clinical depression of 13 on the GDS.[83] An even higher proportion of service users displayed significant anxiety symptoms, with 73% scoring at or above the cut-off value for

TABLE 17 Clinical scores at baseline by trial arm: service user ratings

Measure[a]	Score range	Control	Intervention	Total
PI[a]	0–75	44 (15)	43 (19)	44 (17)
PACS[b]	0–100	25 (16, 41)	25 (15, 38)	25 (16, 40)
ComQoL[b]	–140 to 140	105 (76, 125)	100 (77, 129)	102 (76, 126)
GDS[b]	0–40	9 (5, 13)	10 (6, 16)	10 (6, 14)
GDS > 13[c]	N/A	28.4 (25/85)	38.9 (35/90)	34.3 (60/175)
GAS[a]	0–54	18 (9)	19 (10)	18 (10)
GAS > 13[c]	N/A	72.1 (62/86)	74.4 (67/90)	73.3 (129/176)
RSES[b]	6–30	26 (22, 29)	25 (22, 28)	26 (22, 28)

N/A, not applicable.

a Mean score [standard deviation (SD)]. SD corrected for clustering at centre level.

b Median score (IQR).

c Percentage (proportion) scoring above the clinical cut-off (13) for diagnosis of depression or anxiety.

TABLE 18 Clinical scores at baseline by trial arm: carer ratings

		Key worker			Home carer		
Measure	Score range	Control	Intervention	Total	Control	Intervention	Total
PI[a]	0–75	33 (14)	32 (12)	33 (13)	30 (13)	31 (14)	30 (13)
PACS[b]	0–100	11 (7 to 21)	13 (4 to 21)	12 (6 to 21)	14 (7 to 19)	7 (1 to 17)	10 (4 to 18)
ABC-H[b]	0–48	8 (4 to 14)	9 (5 to 17)	9 (4 to 16)	10 (4 to 14)	8 (4 to 18)	9 (4 to 16)
ABC-I[b]	0–45	9 (4 to 15)	9 (5 to 15)	9 (4 to 15)	10 (6 to 18)	12 (4 to 21)	10 (5 to 19)
MOAS[b]	0–120	9 (3 to 20)	8 (4 to 22)	8 (3 to 22)	10 (1 to 23)	11 (3 to 23)	10 (1 to 23)
CBS[a]	15–75	46 (8)	48 (9)	47 (9)			

a Mean (standard deviation).

b Median (IQR).

clinical anxiety of 13 on the GAS.[82] However, their satisfaction with life, as assessed by the ComQoL, was somewhat higher than the population average of 75.[77]

The incidence of psychopathology in the present sample – particularly anxiety – was substantially higher than population estimates of the prevalence of depression and anxiety among people with intellectual disabilities, which are, respectively, >4% and 5–10%.[108–110] The association between problem anger and high levels of psychopathology is consistent with previous reports in people with intellectual disabilities[111] and in the general population.[112–114]

Challenging behaviour

Forty-seven service users (26% of the sample) were rated by key workers as meeting the criterion for severe challenging behaviour (either a combined score of >30 on the ABC-H and ABC-I, or more than four behaviours rated at level 3 on these scales).[87] Median MOAS scores were a little lower than those recorded in a trial of neuroleptic drug treatment for aggressive behaviour in people with intellectual disabilities, which reported a median [interquartile range (IQR)] MOAS score of 12 (8–25) at baseline in the placebo-treated group, and a dramatic fall (to a median score of ∼3: considerably lower than the present participants) during subsequent weekly assessments under placebo treatment.[115]

There is a limit to the extent of challenging behaviour that could in principle be observed in this study because most of the services from which participants were recruited would often exclude individuals who are overtly challenging. Nevertheless, the 26% of participants who met the criterion for severe challenging behaviour is higher than the proportion among the general population supported by the participating services. Mean ABC scores were about 30% higher than those reported in an unselected sample of individuals attending comparable services.[116] Using the same criterion, rates of severe challenging behaviour have been reported to be 15% in the general population of people with intellectual disabilities[117] and 22% in residential services.[118] These figures include individuals with severe and profound disabilities and people who challenge at a level that cannot be managed within many services providing day activities. Neither of these groups would have been eligible for the present study: the former group because they would not have been able to consent and the latter because they would have been excluded, which the present participants, by definition, were not. The high level of challenging behaviour among the present sample is not surprisingly, given the well-described relationship between anger and challenging behaviour among people with intellectual disabilities.[15,17,28]

Regional differences

Baseline scores differed somewhat between regions (*Tables 19* and *20*). Service users in Scotland rated themselves, and were rated by both groups of carers, as less angry than service users in England or Wales, and they were rated by themselves and their home carers as having fewer anger coping skills. Service users in England had higher levels of psychopathology, and were significantly more likely to meet criteria for a diagnosis of depression or anxiety. They were more challenging than Scottish participants on all three challenging behaviour measures and Welsh participants on two of the three measures. This reflects the differences between regions in the types of services recruited to the trial, which, in England, included some secure settings and only a single local authority day service.

TABLE 19 Clinical scores at baseline by region: service user ratings

Measure	Score range	Service user in: England	Scotland	Wales	Statistic	*p*-value
PI[a]	0–75	45.8 (16.2)	36.8 (19.1)	49.0 (16.9)	$F(2,180) = 8.86$	< 0.001
PACS[b]	0–100	26 (16, 39)	19 (9, 27)	35 (23, 49)	$\chi^2(2) = 22.4$	< 0.001
GDS[b]	0–40	11 (7, 20)	9 (5, 13)	9 (5, 14)	$\chi^2(2) = 8.6$	< 0.001
GDS > 13[c]	N/A	45.0 (27/60)	26.6 (17/64)	31.4 (16/51)	$\chi^2(2) = 4.9$	< 0.09
GAS[b]	0–54	22.0 (9.6)	16.5 (9.7)	16.3 (9.8)	$F(2,175) = 6.70$	< 0.002
GAS > 13[c]	N/A	86.7 (52/60)	66.2 (43/65)	66.7 (34/51)	$\chi^2(2) = 8.3$	< 0.02
RSES[b]	6–30	23 (21, 27)	27 (24, 29)	25 (22, 28)	$\chi^2(2) = 13.3$	< 0.001
COMQoL[b]	–140 to 140	100 (76, 130)	100 (68, 121)	110 (88, 132)	$\chi^2(2) = 2.52$	NS

N/A, not applicable; NS, non-significant.

[a] Mean score [standard deviation (SD)]. SD corrected for clustering at centre level.

[b] Median score (IQR).

[c] Percentage (proportion) scoring above the clinical cut-off (13) for diagnosis of depression or anxiety.

TABLE 20 Clinical scores at baseline by region: carer ratings

Measure	Score range	England	Scotland	Wales	Statistic	*p*-value
Key worker						
PI[a]	0–75	36.1 (12.1)	26.6 (15.8)	35.9 (12.5)	$F(2,179) = 12.5$	<0.001
PACS[b]	0–100	11 (6, 21)	11 (4, 23)	14 (8, 21)	$\chi^2(2) = 1.75$	NS
ABC-H[b]	0–48	13 (7, 19)	8 (4, 15)	15 (1, 12)	$\chi^2(2) = 18.2$	<0.001
ABC-I[b]	0–45	13 (9, 22)	9 (5, 14)	5 (1, 9)	$\chi^2(2) = 42.4$	<0.001
MOAS[b]	0–120	23 (10, 34)	5 (2, 16)	7 (2, 13)	$\chi^2(2) = 42.2$	<0.001
CBS[a]	15–75	44.6 (11.6)	47.7 (7.8)	49.5 (10.2)	$F(2,180) = 5.0$	<0.01
Home carer						
PI[a]	0–75	32.5 (17.2)	33.8 (11.2)	23.2 (9.1)	$F(2,126) = 10.4$	<0.001
PACS[b]	0–100	17 (8, 20)	4 (0, 13)	12 (7, 18)	$\chi^2(2) = 16.8$	<0.001
ABC-H[b]	0–48	10 (6, 16)	4 (2, 12)	12 (6, 16)	$\chi^2(2) = 10.1$	<0.01
ABC-I[b]	0–45	14 (9, 23)	7 (4, 16)	9 (4, 18)	$\chi^2(2) = 10.6$	<0.005
MOAS[b]	0–120	22 (16, 31)	5 (1, 15)	3 (0, 11)	$\chi^2(2) = 32.2$	<0.001

NS, non-significant.

a Median score (IQR).

b Mean score (standard deviation).

Relationship of baseline anger ratings to other clinical variables

Previous research has reported correlations between staff ratings on the Anger Inventory, a measure similar to the PI, and a range of measures of challenging behaviour rated by the same staff, including the ABC.[116] Changes in self-reported depression have also been shown to be related to self-reports of anger on the Anger Inventory,[38] suggesting an association between self-reported anger and the self-report of other psychological difficulties. On the basis of these earlier studies, we predicted that the service user's own anger ratings would be related to other subjective measures of mental health, but that carers' anger ratings would be related more strongly to the service users' observable challenging behaviour. This was explored by hierarchical linear regression. We also conducted similar regression analyses on ratings of anger coping (PACS); these analyses were exploratory, with no predictions.

The data reported are for participants for whom complete data were available for all of the variables included in the analyses (service users, $n = 163$; key workers, $n = 113$ reporting on 162 service users; home carers, $n = 114$). Where a key worker acted for more than one service user, the data were treated as though they were independent. On a visual inspection of the residuals and the residuals plotted against the predicted values, there were no obvious outliers in the service user and key worker data sets. There appeared to be one outlier in the home carer data set, but excluding this value did not change the conclusions of the analysis. Multicollinearity checks, using the variance inflation factor, did not identify collinearity issues in any of the models tested.

Correlations between clinical variables

Inter-rater correlations for PI values are shown below the diagonal in *Table 21*. Service user PI ratings were only marginally correlated with carer ratings, but the correlation between the two carer ratings was much larger, suggesting that key workers and home carers see service user anger similarly to one another, but differently from the service user's self-perception.

Inter-rater correlations for the PACS are shown above the diagonal in *Table 21*. All correlations were significant but small ($0.01 < p < 0.05$). PI and PACS ratings were significantly correlated for service users ($r = 0.217$, $p = 0.005$) but not for key workers ($r = -0.076$) or home carers ($r = 0.122$), again suggesting a difference between carer perceptions of service users and service user self-perceptions.

Service user ratings on the three mental health measures were significantly intercorrelated (all $p < 0.001$). The highest correlation was between the depression and anxiety scores (GDS vs GAS: $r = 0.697$); correlations with self-esteem (RSES) were somewhat lower ($r = -0.384$ and -0.302, respectively).

Similarly, both sets of carer ratings on the three challenging behaviour measures were all strongly intercorrelated, as shown in *Table 22* (all $r > 0.446$, $p < 0.001$). The correlations between key worker and home carer ratings were highly significant for the MOAS ($r = 0.486$, $p < 0.001$), less so for the ABC-I ($r = 0.243$, $p < 0.01$) and not quite significant for the ABC-H ($r = 0.176$, $p = 0.059$).

All three key worker ratings of challenging behaviour were significantly correlated with their ratings on the CBS (ABC-H: $r = 0.173$, $p < 0.02$; ABC-I: $r = 0.188$, $p < 0.02$; MOAS: $r = 0.148$, $p < 0.05$), indicating that service users who were seen as more able to control their challenging behaviour were rated as more challenging. Key workers' CBS ratings were not significantly related to age ($r = 0.044$), IQ ($r = 0.133$) or gender ($t = 1.1$).

Regression analyses

The regression analyses for the three sets of PI ratings are summarised in *Table 23a* and *b*, with the significant predictors that are discussed below highlighted. The regression analyses for the PACS did not identify any significant predictors and these data are not reported.

For service users, demographic variables were a marginally significant predictor of PI ratings (block 1, $p = 0.047$), and the model improved very significantly when mental health variables were added (block 2, $p < 0.001$); adding challenging behaviour variables (block 3) did not significantly improve the model. The significant predictors were age (older service users rated themselves as less angry) and anxiety. As anxiety and depression were highly intercorrelated, the latter may be taken as a proxy for poor mental health.

TABLE 21 Inter-rater correlations of PI and PACS ratings[a]

		Service user		Key worker		Home carer		
	Rater	*r*-value	*p*-value	*r*-value	*p*-value	*r*-value	*p*-value	
PI	Service user	–	–	0.187	0.017	0.195	0.036	PACS
	Key worker	0.158	0.044	–	–	0.218	0.019	
	Home carer	0.174	0.062	0.356	<0.001	–	–	

a Correlations for the PI are shown below the diagonal; correlations for the PACS are shown above the diagonal.

TABLE 22 Intercorrelations between challenging behaviour measures

	Key workers		Home carers	
Measure	ABC-H	ABC-I	ABC-H	ABC-I
ABC-I	0.664		0.687	
MOAS	0.446	0.632	0.512	0.707

TABLE 23a Predictors of PI score at baseline[a]

		Model					
		Service user (*n* = 163)		Key worker (*n* = 162)		Home carer (*n* = 114)	
Block	Variable	β	*p*-value	β	*p*-value	β	*p*-value
1. Demographics	Age of service user	–0.27	**0.029**	0.00	0.963	–0.25	**0.034**
	Age of key worker			–0.10	0.309		
	Age of home carer					–0.19	0.022
	Gender of service user	4.07	0.169	0.62	0.795	–1.78	0.537
	Gender of key worker			–2.90	0.185		
	Gender of home carer					–0.30	0.910
	FSIQ	0.17	0.343	0.36	**0.010**	0.60	**0.003**
2. Demographics and mental health scores	Age of service user	–0.26	**0.033**	0.01	0.920	–0.31	**0.010**
	Age of key worker			–0.12	0.233		
	Age of home carer					–0.16	0.069
	Gender of service user	5.52	0.052	1.29	0.589	–1.13	0.698
	Gender of key worker			–3.68	0.095		
	Gender of home carer					–2.07	0.440
	FSIQ	0.12	0.494	0.34	**0.014**	0.56	**0.004**
	GDS	0.31	0.257	0.58	**0.007**	0.50	0.053
	GAS	0.42	**0.020**	–0.10	0.479	0.04	0.812
	RSES	–0.01	0.987	–0.02	0.945	0.15	0.654
3. Demographics, mental health and challenging behaviour scores	Age of service user	–0.28	**0.027**	–0.06	0.556	–0.27	**0.015**
	Age of key worker			–0.01	0.911		
	Age of home carer					–0.06	0.475
	Gender of service user	5.90	0.052	2.40	0.320	–1.79	0.499
	Gender of key worker			–4.12	0.052		
	Gender of home carer					–4.71	0.085
	FSIQ	0.11	0.506	0.39	**0.003**	0.54	**0.004**
	GDS	0.29	0.318	0.26	0.244	0.36	0.135
	GAS	0.42	**0.019**	–0.10	0.473	0.03	0.858
	RSES	0.04	0.913	–0.02	0.945	0.26	0.404
	ABC-H (key worker)	–0.16	0.401	0.05	0.721		
	ABC-H (home carer)					0.10	0.587
	ABC-I (key worker)	0.08	0.759	0.42	**0.044**		
	ABC-I (home carer)					0.22	0.288
	MOAS (key worker)	0.04	0.761	0.10	0.334		
	MOAS (home carer)					0.26	**0.044**

a Beta (β) is the regression coefficient and refers to the change in outcome per one unit change in covariate.

TABLE 23b Predictors of PI score at baseline[a]

Summary of PI models: goodness-of-fit measures							
Model	F	df	*p*-value (model)	R^2	Adjusted R^2	R^2 change	*p*-value (change)
Service user							
Block 1	2,71	3,162	**0.047**	0.049	0.031	0.049	**0.047**
Block 2	5.03	6,162	**< 0.001**	0.162	0.130	0.113	**< 0.001**
Block 3	3.39	9,162	**0.001**	0.166	0.117	0.004	0.851
Key worker							
Block 1	1.98	5,161	0.084	0.060	0.030	0.060	0.084
Block 2	2.72	8,161	**0.008**	0.125	0.079	0.065	**0.012**
Block 3	3.74	11,161	**< 0.001**	0.215	0.158	0.091	**0.001**
Home carer							
Block 1	4.52	5,113	**0.001**	0.173	0.135	0.173	**0.001**
Block 2	3.85	8,113	**0.001**	0.227	0.168	0.054	0.069
Block 3	5.61	11,113	**< 0.001**	0.377	0.310	0.150	**< 0.001**

Significant *p*-values are shown in bold type.

For both key workers and home carers, IQ was a significant predictor of their PI ratings, with more able service users rated as more angry. For key workers, the addition of mental health variables significantly improved the model (block 2, $p = 0.012$), reflecting a significant effect of depression ($p = 0.007$). Depression was also almost significant in the home carer model ($p = 0.053$). However, for both sets of carers, the effect of depression disappeared when challenging behaviour was added to the model (block 3, $p < 0.001$), with significant prediction of PI by ABC-I scores (key workers) and MOAS scores (home carers). Again, given the high intercorrelations between challenging behaviour measures (see *Table 23*), we interpret these results to mean that challenging behaviour was a more important predictor of PI ratings than their perceptions of the service user's mental health for both sets of carers. The significant effect of GDS score in block 2 but not block 3 of the key worker model probably reflects the fact that these ratings were significantly correlated with key worker ABC-I scores ($r = 0.348$, $p < 0.001$).

A further predictor in the home carer model was age, which was significant in all three stages of the analysis: older service users were rated as less angry, consistent with service users' self-ratings. However, this relationship was not present in key worker ratings.

The outcomes of these analyses are summarised in *Figure 2*. Older service users were rated as less angry by service users and home carers but not by key workers; more intellectually able service users were rated as more angry by both sets of carers but not by the service users themselves; and, as predicted, the clinical factor most strongly associated with PI ratings was mental health status for service users and challenging behaviour for carers. The regression models account for a relatively small proportion of the overall variance (12–31%), but this is not surprising considering that the models did not include any variables directly related to the service users' personal history or environment.

Age

To the best of our knowledge, this is the first study to report associations between age and anger in people with intellectual disabilities. However, the decline in anger with age is consistent with the literature on challenging behaviour, which is known to increase during childhood, with a peak in young adulthood and

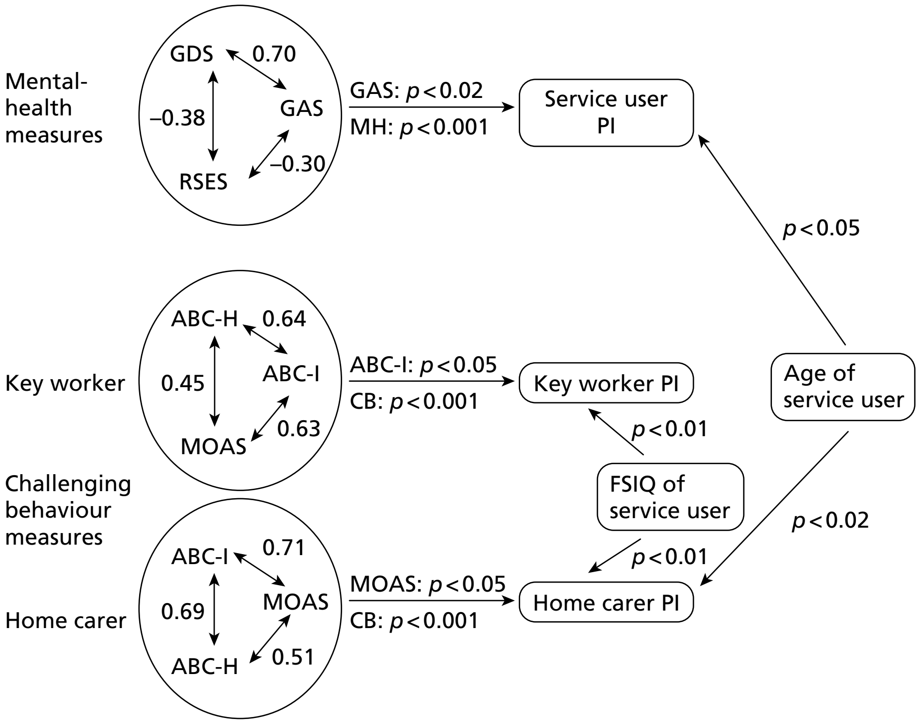


FIGURE 2 Predictors of PI scores. Within the circles are shown the intercorrelations between measures of mental health (MH, above) and challenging behaviour (CB, below). The arrows to the right of the circles show the individual measures (above the arrow) and blocks of data (below the arrow) that significantly predict PI scores. Other significant predictors (age and IQ) are shown to the right.

a subsequent decline.[119,120] There are several reports in the general population that adults experience anger less frequently and intensely with increasing age,[121–123] express anger less destructively,[124–126] and are less prone to attribute anger to others.[127] The decrease in anger with age reported by service users and their home carers is consistent with these studies and extends the observation of decreasing anger with age to people with intellectual disabilities. However, although the age-related decline in anger was reported by the service users themselves and their home carers, it was not reported by their key workers. We have no explanation for this difference.

Intellectual ability

We are not aware of any previous studies of the prevalence of anger in relation to IQ. There have been a number of studies of aggressive challenging behaviour in relation to IQ but these are inconsistent: they include reports of an increase,[119,128,129] no change[130–132] or a decrease[120] in aggression as the degree of intellectual impairment increases. (We did not observe any relationship between challenging behaviour and IQ, perhaps because the IQ range was narrower than in previous studies, which, unlike the present study, also included people with severe and profound disabilities.) One potential explanation of the positive relationship between anger and IQ is that staff may consider more able service users to have more effective control over their aggressive behaviour, which, for example, would enable more intellectually able service users to express their anger in more sophisticated ways, such as planned aggression or acts of revenge. A relationship between control and IQ is suggested by the finding of Tynan and Allen[133] that staff judged individuals with ‘mild disabilities’ to be more in control of their physically aggressive behaviour than individuals with ‘severe disabilities’ who displayed similar behaviour. Indeed, we did find small correlations indicating that service users who were rated as more in control of their behaviour were also rated as somewhat more challenging. A similarly sized correlation (albeit non-significant because the sample was smaller) was reported by Mills and Rose.[134] However, although there was a small correlation between key worker ratings of controllability and severity of challenging behaviour, we found no relationship between controllability ratings and IQ, consistent with earlier studies.[135,136] Therefore, increased control cannot explain why more able service users were rated as more angry. Alternatively, the relationship between anger and IQ could be artefactual. Some of the items on the PI refer to relatively subtle social threats that carers may feel would not be understood by less able service users (e.g. 'being charged too much money for getting something fixed'); other things being equal, low scores on these particular items would lead to less able service users receiving a lower overall score.

Mental health and challenging behaviour

The most important finding from this analysis was that, as predicted from earlier data,[38,116] service users and carers use different constructs when rating the service user's anger. Service users rate their behaviour on the basis of their internal emotional state and mental health, as reflected by their ratings of anxiety and depression, whereas carers (both key workers and home carers) rate service users' anger on the basis of overt behaviours, as measured by the challenging behaviour scales. As previously reported,[116] there was a very low correlation between service user and carer anger ratings, which in this study accounted for <3% of the variance. This is not surprising considering that the two ratings are based on differing sets of variables and perceptions. Interestingly, in the earlier study,[116] service user and carer anger ratings became highly correlated ($r = 0.61$) after the service user and carer had attended an anger management course together. On similar lines, staff supporting service users attending individual CBT sessions made little mention of service users' inner lives or well-being when interviewed about their expectations of therapy, but showed more awareness of these issues when interviewed after the therapy.[137] These findings suggest that carers can become more attuned to the service user's subjective experiences, if they attend therapeutic activities together.

Characteristics of retained participants and dropouts

As reported in *Figure 1*, 143 of the 181 service users initially assessed (79%) were successfully followed up at 10 months (with available primary outcome data). The characteristics of service users retained in the trial and those who dropped out are shown in *Table 24*. There was no significant difference between the two groups in demographic variables, degree of disability, or clinical status at the start of the trial, but the groups differed in their accommodation arrangements ($p < 0.05$). Dropouts were less likely to be living in the family home and more likely to be living in staffed (including hospital) or supported accommodation. This primarily reflects the loss from the trial of two services (one hospital and one group home) in the region that mainly recruited day services that were part of residential services, rather than differential dropout of individual participants.

TABLE 24 Characteristics of service users with and without a response to the primary outcome (self-reported PI score at the 10-month follow-up)

Characteristics	Response ($n = 143$)	No response ($n = 38$)	p-value
Demographics			
Age (years)[a]	37 (28 to 46)	39 (28 to 49)	0.504
Gender, % M (proportion)	70 (100/143)	74 (28/38)	0.651
Female[b]	30 (43/143)	26 (10/38)	
Accommodation			
Family home[b]	47 (63/135)	21 (7/34)	0.029
Staffed group home/supported living[b]	34 (46/135)	53 (18/34)	
Independent housing[b]	9 (12/135)	9 (3/34)	
NHS or independent sector hospital[b]	5 (7/135)	15 (5/34)	
Other[b]	5 (7/135)	3 (1/34)	
Learning disability indicators			
FSIQ[a]	57 (53 to 62)	56 (54 to 62)	0.531
BPVS[c]	102.5 (31.98)	98.5 (27.35)	0.495
Total ABS score[c]	83.9 (15.29)	87.9 (16.24)	0.196
Baseline clinical variables			
PI[c]	43.5 (17.47)	43.7 (16.79)	0.955
PACS[a]	25 (16 to 40)	25 (13 to 42)	0.955
GDS[a]	9 (6 to 14)	10 (7 to 20)	0.138
GAS[c]	17.9 (9.56)	19.7 (10.85)	0.323
RSES[a]	26 (22 to 28)	25 (21 to 28)	0.129
COMQoL[a]	101 (75 to 127)	108 (77 to 120)	0.967

a Median score (IQR), with p-value for a non-parametric Mann–Whitney U-test.
b Percentage (proportion), with p-value for a chi-squared test.
c Mean score (standard deviation), with p-value for an independent samples t-test.

Chapter 4 Delivery of the intervention

Scheduling of groups

Fourteen treatment groups were delivered in the main study: five each in regions 1 (Scotland) and 3 (Wales) and four in region 2 (England). The 15th centre that was selected for intervention (#210) withdrew immediately following randomisation. For each remaining intervention group, *Table 25* shows the time (days) between randomisation and lay therapist training, between staff training and the first group session, and from the first to the 12th group session (the minimum possible time to deliver 12 sessions being 77 days). For each control group, *Table 25* shows the interval between training and session 1, and between sessions 1 and 12, with training taking place after the 10-month follow-up assessments of the main trial. The first follow-up assessment was planned for a 2-week window, which for the intervention groups was 16–18 weeks (maximum 126 days) after randomisation and for the control groups was 16–18 weeks (maximum 126 days) after lay therapist training.

Training was delivered to 13 of the 14 intervention groups between 2 and 18 days after randomisation. For these groups, sessions commenced within 2 weeks of lay therapist training and concluded in a maximum of 16 weeks. For 11 groups, it was possible to conduct the 16-week follow-up assessments, as planned, following the end of the group. For a further two groups (#309, #311), the 16-week follow-up assessment took place with one or two groups sessions still to run. This had no effect on whether or not service users were designated as compliant with the intervention, as all participants in both groups (apart from one who dropped out early on) had completed more than eight sessions at this point. For the remaining group (#107), training was delayed for 4 months because of staffing problems, and as a result, the 16-week follow-up for this group took place before the intervention commenced. Once started, this group took several weeks longer to run than any of the other groups, and ended shortly before the 10-month follow-up assessment.

For the control groups, there were much longer delays between lay therapist training and the first group session (median 28 days, compared with 9 days in the intervention group: Mann–Whitney U-test $= 32$, $p < 0.001$). Subsequently, two of the groups failed to complete and were lost to follow-up (#203, #211), and follow-up data collection could not be arranged for a third, which had the longest completion time (#109). For four of the remaining 11 groups, the follow-up assessment was conducted before the end of the group. Two of these groups (#201, #302) were close to completion, and all service users had already met the criterion for compliance with the intervention (eight sessions attended). For the other two groups, the follow-up assessment took place after five (#204) and nine (#108) sessions, respectively.

Attendance at sessions

Engagement with the study by individual service users is summarised in *Table 26*. Columns 3 and 4 refer to the main study, and show the proportion and number of participants in each intervention group who met the criterion for compliance with the intervention by attending 8 of the 12 sessions, and those in every group who provided 10-month follow-up data. Columns 5 and 6 refer to the pre–post study, and show the proportion and number of participants in each control group who met the criterion for compliance when they later received the intervention, and those providing 16-week follow-up data. Groups where there were significant problems with data collection are highlighted in bold text. The totals at the foot of the table summarise the data (1) for all centres and (2) excluding centres that were lost to the study.

Centres highlighted in bold text are those in which there were significant difficulties in data collection.

TABLE 25 Scheduling of groups (days)

Centre	Randomisation to training	Training to session 1	Delivery of 12 sessions	Total[a]
Intervention groups				
101	7	8	84	99
103	18	7	91	116
104	5	7	77	89
107	120	14	140	**274**
110	2	4	108	114
205	8	12	91	111
206	11	10	84	105
207	10	7	91	108
209	4	11	77	92
301	15	12	91	118
305	4	14	105	123
308	15	7	98	120
309	16	6	112	**134**
311	16	13	98	**127**
Median (range)	11 (2 to 120)	9 (4 to 14)	91 (77 to 140)	115 (89 to 274)
Control groups				
102		14	84	98
105		6	77	83
106		16	94	110
108		43	105	**148**
109		51	116	**167**
201		5	126	**131**
203		42		
204		76	91	**167**
211		28		
302		29	112	**141**
303		42	77	119
306		15	84	99
307		13	91	104
310		28	79	107
Median (range)		28 (5 to 42)	91 (77 to 126)	115 (83 to 167)

[a] Totals shown in bold text are outside the 16- to 18-week (126 days) planned assessment window.

TABLE 26 Compliance with the intervention and availability of follow-up data

Centre	*n*	Complied	10-month follow-up data available	Complied	16-week follow-up data available
Intervention groups					
101	8	62.5 (5/8)	62.5 (5/8)		
103	7	85.7 (6/7)	100.0 (7/7)		
104	6	100.0 (6/6)	83.3 (5/6)		
107	5	**40.0 (2/5)**	**60.0 (3/5)**		
110	8	87.5 (7/8)	87.5 (7/8)		
205	5	100.0 (5/5)	100.0 (5/5)		
206	6	50.0 (3/6)	33.3 (2/6)		
207	6	83.3 (5/6)	66.7 (4/6)		
209	7	100.0 (7/7)	100.0 (7/7)		
210	5	**0.0 (0/5)**	**0.0 (0/5)**		
301	6	100.0 (6/6)	83.3 (5/6)		
305	4	50.0 (2/4)	100.0 (4/4)		
309	5	80.0 (4/5)	80.0 (4/5)		
308	7	57.1 (4/7)	100.0 (7/7)		
311	6	100.0 (6/6)	100.0 (6/6)		
Control groups					
102	4		75.0 (3/4)	75.0 (3/4)	75.0 (3/4)
105	5		100.0 (5/5)	60.0 (3/5)	80.0 (4/5)
106	7		71.4 (5/7)	71.4 (5/7)	71.4 (5/7)
108	8		100.0 (8/8)	50.0 (4/8)	62.5 (5/8)
109	7		71.4 (5/7)	**28.5 (2/7)**	**0.0 (0/7)**
201	6		83.3 (5/6)	66.6 (4/6)	83.3 (5/6)
203	6		50.0 (3/6)	**0.0 (0/6)**	**0.0 (0/6)**
204	7		85.7 (6/7)	57.1 (4/7)	57.1 (4/7)
208	5		**0.0 (0/5)**	**0.0 (0/5)**	**0.0 (0/5)**
211	7		100.0 (7/7)	**0.0 (0/7)**	**0.0 (0/7)**
302	4		75.0 (3/4)	50.0 (2/4)	50.0 (2/4)
303	4		75.0 (3/4)	25.0 (1/4)	75.0 (3/4)
306	5		100.0 (5/5)	100.0 (5/5)	100.0 (5/5)
307	8		100.0 (8/8)	87.5 (7/8)	100.0 (8/8)
310	7		85.7 (6/7)	71.4 (5/7)	85.7 (6/7)

continued

TABLE 26 Compliance with the intervention and availability of follow-up data (*continued*)

Centre	*n*	Complied	10-month follow-up data available	Complied	16-week follow-up data available
Total					
Intervention		74.7 (68/91)	78.0 (71/91)		
Control			80.0 (72/90)	50.0 (45/90)	55.5 (50/90)
Total excluding centres lost to follow-up					
Intervention		79.1 (68/86)	82.6 (71/86)		
Control			84.7 (72/85)	66.2 (43/65)	76.9 (50/65)

Excluding the centre that withdrew immediately after randomisation, 79.1% of participants in the intervention group met the criterion for compliance with the intervention, and over 80% of participants in both arms of the trial provided 10-month follow-up data. As described above, a second centre (#107) was very slow to start, with the result that the 16-week follow-up was conducted before the group had met. The data for this group were included in the main analysis, which was analysed on an intention-to-treat basis, but were excluded from the pre–post study.

One of the control groups (#208) was withdrawn from the study because the centre closed down, and as described above, two centres (#203 and #211) subsequently failed to complete the intervention and another centre (#109) was lost to follow-up. Excluding those four centres, the proportion of service users successfully followed up after they received the intervention was somewhat lower than in the intervention groups (76.9% vs 82.6%) and the proportion meeting the criterion for compliance with the intervention was substantially lower (66.2% vs 79.1%).

Costs of the intervention

Details of the sessions delivered in the main study are summarised in *Table 27*. All groups received 12 treatment sessions. Sessions were attended by just under five service users on average (mean attendance per treatment group ranged from 3.1 to 6.8 in Scotland with an overall mean of 5.1, 2.8 to 6.5 in England with an overall mean of 4.8, and 2.8 to 6.6 in Wales with an overall mean of 4.8). Most service users who joined groups would ordinarily have attended the day service (i.e. would have received treatment as usual) and only in Wales was there a sizeable minority of group participants who were additional to those ordinarily attending the service. Mean therapist numbers varied between 1.9 and 2.3 per group, and mean session lengths varied between 1 hour 35 minutes and the planned time of 2 hours, most being at, or near, the latter.

The time input of the consultant psychologists, clinical psychologists and administrative support, together with telephone calls and photocopying, were assessed at regional level as they could not all be allocated to separate treatment groups (*Table 28*). Lay therapist time input in preparing for and running the treatment groups and related travel costs were assessed separately for each treatment group (*Table 29*).

Costs of input from the consultant and clinical psychologists, together with the costs of administrative support, related travel, telephone calls, photocopying and other consumables per region are shown in *Table 30*. These central regional costs averaged across treatment groups were £3633.34 divided by five (i.e. £726.67) in region 1 (Scotland), £3383.09 divided by four (i.e. £845.77) in region 2 (England) and £6145.26 divided by five (i.e. £1229.05) in region 3 (Wales).

TABLE 27 Characteristics of the intervention groups

Group	No. of sessions	Mean no. of service users/session	Mean no. TAU	Mean no. not TAU	Mean no. of therapists	Mean length (minutes)
Region 1 (Scotland)						
101	12	4.6	4.6	0.0	2.3	105
102	12	5.9	5.9	0.0	2.0	102
103	12	5.2	5.2	0.0	2.1	118
104	12	3.1	3.1	0.0	2.3	101
105	12	6.8	6.1	0.7	2.0	110
Mean	*12*	*5.1*	*5.0*	*0.1*	*2.1*	*107*
Region 2 (England)						
201	12	4.9	4.9	0.0	2.1	120
202	12	2.8	2.8	0.0	2.0	95
203	12	4.8	4.8	0.0	1.9	119
204	12	6.5	6.5	0.0	2.1	120
Mean	*12*	*4.8*	*4.8*	*0.0*	*2.0*	*114*
Region 3 (Wales)						
301	12	5.2	2.8	2.3	2.0	120
302	12	2.8	2.8	0	2.0	120
303	12	4.9	4.1	0.8	2.2	120
304	12	4.3	4.3	0	2.2	120
305	12	6.6	4.6	2.0	1.9	120
Mean	*12*	*4.8*	*3.7*	*1.0*	*2.0*	*120*

TABLE 28 Clinical psychology and administrative time input (hours), telephone calls and photocopying per region

Region	Hours			No. of telephone calls	Length of telephone calls, minutes[a]	No. of photocopies[b]
	Consultant psychologist	Clinical psychology	Administrative			
1 (Scotland)	10	122	14	12	60	7107
2 (England)	36	57	20	4	240	6500
3 (Wales)	13	158	92	8	65	7325

a All calls combined.

b Includes 6300 photocopies undertaken centrally in the production of 90 manuals, allocated at the rate of 2100 photocopies (30 manuals) per region.

TABLE 29 Therapist input (hours) to treatment groups and related travel costs

Group	Total therapist hours	Related travel costs (£)
Region 1 (Scotland)		
101	87	0.0
102	80	0.0
103	78	0.0
104	107	0.0
105	77	0.0
Mean	*86*	*0.0*
Region 2 (England)		
201	94	26.60
202	69	115.20
203	82	0.0
204	81	0.0
Mean	*82*	*35.45*
Region 3 (Wales)		
301	117	0.0
302	127	54.0
303	149	29.6
304	136	16.8
305	106	19.2
Mean	*127*	*23.92*

TABLE 30 Costs of clinical psychology and administrative input per region (£)

	Cost (£)		
	Region 1 (Scotland)	Region 2 (England)	Region 3 (Wales)
Consultant psychologist	466.90	1680.84	606.97
Related travel	1.84	0.00	0.00
Clinical psychologist	2587.62	1208.97	3351.18
Related travel	124.36	36.28	1036.87
Administrative input	127.82	182.60	839.96
Telephone calls	3.60	14.40	3.90
Photocopies	296.28	260.00	293.00
Consumables	24.92	0.00	13.38
Total	3633.34	3383.09	6145.26

Table 31 shows the cost of lay therapist input (see *Appendix 2*, *Table 65*) and related travel costs per treatment group together with these distributed central regional costs. *Table 31* also gives a cost per service user for each hour of treatment for each group. The mean hourly cost of intervention per service user was £25.26.

The staff cost of treatment as usual was £14.07 per hour (see *Appendix 2*, *Table 65*). The mean number of service users in a group was 4.9. Intervention replaced treatment as usual for a mean of 4.5 service users. Therefore, the mean hourly excess cost of intervention compared with treatment as usual was £25.26 − (£14.07 × 4.5/4.9) = £12.34.

TABLE 31 Cost of treatment groups: lay therapist, related travel costs and central regional costs (£) and overall cost per service user hour

	Cost (£)						
Group	Therapist input	Related travel	Central regional[a]	Total	Total length of sessions (hours)	Mean no. of service users	Cost per service user hour (£)
Region 1 (Scotland)							
101	1386.78	0.00	726.67	2113.45	21.0	4.6	21.88
102	1275.20	0.00	726.67	2001.87	20.4	5.9	16.63
103	1243.32	0.00	726.67	1969.99	23.6	5.2	16.05
104	1705.58	0.00	726.67	2432.25	20.2	3.1	38.84
105	1227.38	0.00	726.67	1954.05	22.0	6.8	13.06
Region 2 (England)							
201	1498.36	26.60	845.77	2370.73	24.0	4.9	20.16
202	1099.86	115.20	845.77	2060.83	19.0	2.8	38.74
203	1307.08	0.00	845.77	2152.85	23.8	4.8	18.84
204	1291.14	0.00	845.77	2136.77	24.0	6.5	13.70
Region 3 (Wales)							
301	1864.98	0.00	1229.05	3094.03	24.0	5.2	24.79
302	2024.38	54.00	1229.05	3307.43	24.0	2.8	49.22
303	2375.06	29.60	1229.05	3633.71	24.0	4.9	30.90
304	2167.84	16.80	1229.05	3413.69	24.0	4.4	32.33
305	1689.64	19.20	1229.05	2937.89	24.0	6.6	18.55

[a] Costs for clinical psychology and administrative input per region (from *Table 30*) allocated evenly per group.

Chapter 5 Fidelity of the intervention

A total of 52 sessions were monitored. For logistical reasons, two visits fell outside the planned time windows. In a first wave of monitoring, 28 sessions (14 groups) in the intervention arm of the trial were observed. The inter-rater reliability of those data was examined, leading to clarification of the criteria for a small number of items (see *Inter-rater reliability*, below). This was followed by a second wave of monitoring visits to 24 sessions (13 groups) in what had previously been the control arm of the trial. In all, 15 pairs of monitors provided data: six pairs observed a single session and nine pairs observed multiple (2–11) sessions (median = 2).

Inter-rater reliability

Inter-rater reliability was calculated on the basis of all sessions that were jointly monitored ($n = 49$: three sessions were monitored by a single observer).

Inter-rater reliability for the first wave of monitoring sessions (intervention groups) was generally good (83% overall agreement: *Table 32*). However, five individual items were identified as less reliable, defined as interobserver agreement <0.75 and $\kappa<0.6$. The scoring required the observers to rate whether or not an aspect of the intervention was applicable, in addition to whether it was present or absent. The problems with the less reliable items were identified as arising partly from difficulties in making absent compared with 'not applicable' judgements, and partly in deciding between present and absent. These issues were addressed by defining more strictly when 'not applicable' could be used, and defining the criteria for present/absent more precisely. For example, item 7.iii, 'Considered the link between elicited cognitions and affect' was clarified as 'This involves reflecting back on the emotional implications of cognitions expressed by participants. If 7.i has been scored as 0 (no cognitions were expressed) then this item should be scored as N/A. If 7.i is scored as 1, then 7.iii should be scored as 1 or 0, but not as N/A'. Reliability increased for the five items for which the criteria had been tightened in the second wave of monitoring sessions (delivery of the intervention to the previous control groups) (see *Table 32*).

The overall Cohen's kappa value of 0.65 indicates a 'substantial' level of agreement.[138] Agreement was only 'fair' ($\kappa = 0.28$, 0.37) for two pairs of monitors, who observed a total of three sessions, and 'moderate' ($\kappa = 0.43$–0.54) for three pairs, who observed a total of six sessions. Agreement was 'substantial' ($\kappa = 0.60$–0.75) for the other 10 pairs, who observed a total of 40 sessions.

TABLE 32 Inter-rater reliability for fidelity monitoring sessions

	First wave	Second wave	All groups
Services	14	13	27
Sessions	26	23	49
Overall			
Percentage agreement	83.1	82.3	82.8
Cohen's kappa (95% CI)	0.65 (0.60 to 0.71)	0.64 (0.58 to 0.69)	0.64 (0.60 to 0.68)
Five worst items (3.3, 5.1, 7.3, 8.2, 8.3)			
Percentage agreement	63.0	71.3	66.9
Cohen's kappa (95% CI)	0.44 (0.34 to 0.53)	0.55 (0.43 to 0.68)	0.50 (0.41 to 0.59)

Agreement between individual monitors and their agreed ratings was examined in order to evaluate the extent to which clinical experience influenced the agreed ratings. In 10 pairs one member was a consultant psychologist, and in the other five pairs, one member could be identified as more experienced. Cohen's kappa values were higher for the more experienced monitors ($\kappa = 0.85$) than for the more junior monitors ($\kappa = 0.75$), suggesting that the rating of the more senior monitor was given more weight when resolving discrepancies.

Monitors also demonstrated an excellent level of inter-rater reliability for global ratings of fidelity to the manual (83%), group process (83%), and the principles of CBT (79%), as well as a single overall rating (83%).

Consistency

The consistency of the scale was calculated based on agreed ratings where available ($n = 49$) or single ratings where not ($n = 3$). 'Not applicable' scores were treated as missing values and the value was set to the mean of all present/absent ratings for that item. Consistency was high (Cronbach's alpha = 0.864). Five items (2.i, 5.ii, 7.iii, 8.ii and 20.iii) had item total correlations of < 0.2, but the effect on Cronbach's alpha of removing individual items was minimal (range 0.854–0.872).

Factor structure

For the factor analysis, 'not applicable' ratings were permitted for the seven items (each marked with an asterisk) in *Table 5*, and treated as missing values, as above.

Principal components analysis identified 10 factors with eigenvalues of > 1, accounting for 73% of the variance in MAGIC scores. The scree plot indicated a single major factor that accounted for 25% of the variance, with the remaining nine factors accounting for 3–9% each. *Table 33* shows the rotated component matrix, with item loadings > 0.5 shown in bold text and loadings of 0.4–0.5 in bold italic text. It is apparent that with the exception of item 10.iii (which was the least-reported and among the least-reliable items) all of the items contributed to at least one factor, there was relatively little cross-loading, and there were no single-item factors. Taking into account the high level of consistency of the overall scale, the single factor solution identified using the scree plot criterion, and the complexity of the factor structure implied by the eigenvalue criterion, the total MAGIC score, rather than factor scores, was used to evaluate the fidelity of delivery of the intervention.

Factor content was examined for its descriptive value. *Table 34* lists the highest-loading items for the first five factors, which together accounted for 51% of the variance. The table shows the items with loadings of > 0.5 on the first five factors, which account for just over 50% of the variance. The entries in italic text represent an interpretation of each factor. The main factor, labelled 'communication' as well as factors 2 ('respect') and 4 ('empathy') relate to general group work skills, whereas factors 3 ('management of the session') and 5 ('use of materials') relate to the mechanics of running the group.

Delivery of group sessions

The fidelity of delivery of the intervention, as assessed by the MAGIC, is summarised in *Table 35*. These data are based on (1) agreed fidelity ratings where two observers were present ($n = 48$ sessions), (2) a single observer when only one was present ($n = 3$ sessions) or (3) the more experienced observer rating when there were two observers but no agreed ratings ($n = 1$ session). Where groups were monitored twice ($n = 25$ groups), the average across the two monitoring sessions was taken as the final fidelity score. Where only a single monitoring session was carried out ($n = 2$ groups) this score was taken as the final fidelity score. Items recorded as 'not applicable' were removed from the scoring and the total score was pro-rated to take this into account.

TABLE 33 Factor structure of the MAGIC

Rotated component matrix[a]										
	Component									
Item	1	2	3	4	5	6	7	8	9	10
Q6.iii	**0.869**	–0.057	0.158	0.203	0.140	0.028	–0.005	–0.044	0.069	0.042
Q4.iii	**0.771**	–0.044	0.295	0.093	0.011	0.202	–0.130	0.003	0.127	0.060
Q6.i	**0.733**	0.017	0.027	**0.533**	0.005	0.010	0.131	0.031	0.017	0.029
Q9.iii	**0.632**	***0.489***	0.053	–0.126	0.143	–0.156	0.186	0.061	0.025	0.001
Q4.ii	**0.582**	0.251	0.177	0.054	0.231	0.260	0.229	–0.010	0.040	–0.002
Q3.iii	***0.496***	0.293	–0.046	0.324	***0.471***	–0.007	0.128	–0.199	0.224	0.105
Q9.ii	***0.460***	0.139	–0.197	–0.168	0.299	–0.250	0.161	0.296	0.288	–0.232
Q9.i	0.259	**0.730**	0.225	0.379	0.096	–0.016	0.063	0.089	0.126	0.049
Q5.ii	–0.207	**0.727**	0.002	–0.036	–0.100	0.064	0.010	–0.062	–0.089	0.009
Q7.i	0.145	**0.543**	***0.452***	0.118	–0.058	–0.054	0.097	–0.058	0.220	0.018
Q8.i	0.204	***0.464***	0.075	0.071	–0.059	0.350	0.135	0.283	0.209	0.159
Q5.i	0.123	0.192	**0.753**	0.271	0.054	–0.039	–0.076	0.104	0.186	0.280
Q1.iii	***0.413***	–0.139	**0.629**	–0.286	0.210	–0.136	0.117	0.048	–0.124	–0.079
Q5.iii	0.221	***0.420***	**0.619**	0.094	0.149	0.142	0.104	0.342	0.018	–0.033
Q1.ii	0.123	0.184	**0.504**	0.239	0.316	–0.026	0.171	–0.229	0.140	–0.377
Q3.ii	0.203	0.008	0.089	**0.850**	0.124	0.035	0.125	–0.062	–0.003	–0.032
Q4.i	0.141	**0.519**	0.084	**0.642**	0.123	–0.096	–0.118	0.061	–0.047	0.145
Q10.i	0.070	–0.032	0.133	0.153	**0.797**	–0.101	–0.041	0.236	0.024	–0.028
Q6.ii	***0.401***	–0.172	0.086	0.005	**0.733**	0.211	0.048	–0.194	0.052	0.088
Q10.ii	–0.024	0.214	0.222	0.392	***0.431***	0.090	0.054	0.342	0.071	0.122
Q2.ii	0.188	0.071	0.097	–0.031	0.199	**0.791**	0.142	–0.099	–0.003	0.003
Q2.i	0.057	0.025	0.150	–0.025	0.149	**–0.780**	–0.048	–0.239	0.033	0.085
Q7.iii	0.066	0.007	–0.138	0.014	0.061	0.142	**0.765**	0.206	–0.035	0.041
Q7.ii	0.097	0.121	0.357	0.079	–0.033	0.111	**0.714**	–0.015	0.153	0.056
Q8.ii	–0.056	0.003	0.059	–0.048	0.043	0.115	0.132	**0.778**	–0.037	0.093
Q3.i	0.399	–0.036	0.177	0.308	0.202	–0.193	0.126	***0.433***	0.068	–0.389
Q1.i	0.163	0.060	0.113	–0.017	0.082	0.009	0.001	–0.056	**0.825**	0.060
Q10.iii	0.276	0.312	–0.047	–0.137	0.262	0.269	–0.253	–0.202	–0.367	0.127
Q8.iii	0.129	0.124	0.111	0.040	0.196	0.037	0.050	0.128	***0.466***	**0.674**
Q2.iii	0.053	0.101	0.069	0.159	–0.004	–0.264	***0.473***	0.032	–0.161	**0.603**

a Extraction method, principal component analysis; rotation method, varimax with Kaiser normalisation.

TABLE 34 Interpretation of MAGIC factors

Factor 1: communication	
6.iii	Care was taken to pace the session at a rate that allowed group members to keep up with what was happening
4.iii	Able to shift appropriately between listening and leading
6.i	Discussions were pitched at a level that was understood by all group members
9 iii	Promoted an atmosphere of collaboration between therapists and group members
4.ii	In control of the session, communicated clearly without frequent hesitations/repetitions
Factor 2: respect	
9.i	Encouraged a sense of responsibility and mutual respect among group members
5.ii	Did not criticise, disapprove or ridicule group members' behaviour
7.i	Elicited (or responded to) specific thoughts, assumptions, images, memories, beliefs or perceptions
4.i	Communicated warmth, concern and caring
Factor 3: management of the session	
5.i	Explained rationale and requirements for the different activities/elements of the session clearly
1.iii	Good management of time
5.iii	Responded to seemingly irrelevant interruptions in an effective yet diplomatic manner
1.ii	Agenda was adhered to during the session
Factor 4: empathy	
6.i	Discussions were pitched at a level that was understood by all group members
3.ii	Showed sensitivity by adjusting the content or style of their own communication to help members' understanding
4.i	Communicated warmth, concern and caring
Factor 5: use of materials	
10.i	Reviewed previous week's homework
6.ii	Materials were used appropriately

TABLE 35 Fidelity of delivery of group sessions

		Global ratings (0–10)			
Groups	**Fidelity (%)**	**Manual**	**Group process**	**CBT**	**Overall**
Intervention	68.3	7.5	7.4	5.5	7.0
Control	63.8	7.0	7.5	5.8	6.5
England	67.6	6.6	7.0	5.0	6.3
Scotland	53.8	6.5	6.4	4.5	6.0
Wales	77.5	8.4	8.2	7.2	8.0
Overall	*64.0*	*7.3*	*7.4*	*5.7*	*6.8*

Fidelity varied widely across groups, but the mean score was comparable across the two waves of data collection (intervention 68.3; control 63.8). With the exception of one group in the intervention group that received a very low score (18.7%), the range of scores was also similar in the two arms (intervention 40.2–86.0; control 41.4–83.3). However, there was a marked difference between regions, with groups in Wales scoring higher than those in England, and groups in Scotland scoring lower [$F(2,25) = 7.36$, $p < 0.005$]. The same regional pattern was repeated on each of the four global ratings [manual: $F(2,23) = 4.49$, $p < 0.025$; group process: $F(2,17) = 2.49$, $p = 0.11$; CBT: $F(2,23) = 11.58$, $p < 0.001$; overall: $F(2,23) = 6.56$, $p < 0.01$].

There was a high correlation ($r = 0.88$, $p < 0.001$) between the total fidelity score and the overall global rating. Correlations for global ratings of each of the three elements of the MAGIC were only marginally lower ($r = 0.75$–0.87). Global ratings of fidelity to the principles of CBT were lower than global ratings of fidelity to the manual or to group process. This was seen in both arms of the trial and in all three regions (*Table 36*). Fidelity to CBT received the lowest rating in 23/26 groups, the joint lowest in two, and the second lowest in the other group.

In order to provide a clearer picture of what was and was not achieved in the groups, *Table 36* lists the items that were most frequently (>80%) and least frequently (<40%) observed in the 52 sessions that were

TABLE 36 Delivery of the elements of the intervention[a]

Most present items (>80%)		
3.i	49	Conveyed understanding by rephrasing or summarising what group members said
3.ii	45	Showed sensitivity by adjusting the content or style of their own communication to help members' understanding
4.i	46	Communicated warmth, concern and caring
4.ii	43	In control of the session, communicated clearly without frequent hesitations/repetitions
4.iii	42	Able to shift appropriately between listening and leading
5.ii	44	Did not criticise, disapprove or ridicule group members' behaviour
6.i	46	Discussions were pitched at a level that was understood by most group members
6.ii	46	Materials were used appropriately
6.iii	45	Care was taken to pace the session at a rate that allowed group members to keep up with what was happening
9.ii	45	Promoted interaction between group members and encouraged participation in group activities
9.iii	42	Promoted an atmosphere of collaboration between therapists and group members
10.i	50	Reviewed previous week's homework
Least present items (<40%)		
1.i	8	Set out the agenda for session
2.iii	19	Asked for feedback and reactions to session
10.iii	8	Welcomed members' requests for clarification
7.ii	12	Identified cognitions from members' reports of their problems
7.iii	13	Considered the link between elicited cognitions and affect
8.ii	19	Attempted to help members manage their emotions in sessions
8.iii	20	Made the link between the emotions members expressed in sessions and their particular problems

a The second column shows the number of sessions (maximum = 54) in which the item was rated as present.

monitored. The list of most frequent items demonstrates that overall, the group leaders displayed a high level of group work skills in relation to both engagement of participants and appropriate presentation of information. However, the list of least-frequent items identifies some significant weaknesses. Two of these items (agenda setting and asking for feedback) are routine technical CBT activities that were not explicitly mentioned in the manual; a third, 'welcomed members requests for clarification' was recorded infrequently because few such requests were made. However, the other four low-frequency items related to working with the key targets of CBT, emotions and cognitions, suggesting that the lay therapists were less able to deliver these aspects of the intervention.

As the cognitive elements in particular feature more prominently in the second half of the intervention, we examined the delivery of the 'emotional' and 'cognitive' items separately for early and late monitoring sessions. The overall frequency of the four low-frequency items was similar in earlier ($n = 31$) and later ($n = 33$) sessions, and examination of the individual items provided no evidence that the delivery of the 'emotional' and 'cognitive' aspects of the intervention increased in the second half of the intervention (*Table 37*).

Relationship of fidelity to outcome

As reported in more detail in *Chapter 9*, significant correlations were found between fidelity ratings and post-intervention self-ratings on the PI ($r = 0.43$, $p < 0.001$) and PACS ($r = 0.26$, $p < 0.02$). There also was a significant relationship ($p < 0.001$), in the predicted direction, between fidelity ratings and supervisor predictions of outcome: mean (95% CI) fidelity scores were: predicted best, 74.6 (68.0 to 83.3); predicted intermediate, 72.4 (63.3 to 77.6); and predicted worst, 56.0 (44.8 to 71.1).

Comments on the Manualised Group Intervention Checklist

Reliability and validity

Because the MAGIC was developed within the context of a relatively large cluster RCT, the development is based on the observation of two sessions from each of a large number of therapeutic groups ($n = 27$), by a large number of observers ($n = 16$), working in different paired combinations. The results indicate that the inter-rater reliability of the MAGIC is acceptable, in terms of both the overall score and all of the individual scale items.

TABLE 37 Frequency of 'cognitive' and 'emotional' elements of the intervention in early and late monitoring sessions[a]

Cognition/emotion items		Early	Late
Focus on key cognitions			
7.i	Elicited (or responded to) specific thoughts, assumptions, images, memories, beliefs or perceptions	22	19
7.ii	Identified cognitions from members' reports of their problems	6	6
7.iii	Considered the link between elicited cognitions and affect	4	9
Focus on key emotions			
8.i	Acknowledged the emotions of the members in the course of the session	18	15
8.ii	Attempted to help members manage their emotions in sessions	11	8
8.iii	Made the link between the emotions members expressed in sessions and their particular problems	10	10

[a] No significant difference in frequency was observed for any item. The largest difference was for item 7.iii, for which $p > 0.1$ (Fischer's exact probability test).

In common with the Cognitive Therapy Scale[65] and the CTS-Psy,[66] the MAGIC includes items that address general therapeutic processes (e.g. interpersonal effectiveness), as well as specific CBT skills (e.g. homework issues). Non-specific factors, in particular the therapeutic alliance, are increasingly highlighted in the therapeutic literature as contributing to therapeutic change.[139–142] Therefore, in addition to rating how far therapists abide to the manual, it is also helpful to obtain reliable data about the therapists' overall success in implementing the intervention. Haddock *et al.*[66] presented two subscales for the CTS-Psy, for general skills and technical skills, corresponding roughly to the first and second halves of the instrument. As our factor analysis identified a single-factor solution, we did not compute subscale scores for the MAGIC. However, participants made global ratings of overall quality and of the three areas that the MAGIC was designed to assess: delivery of the manual, attention to group process, and the principles of CBT. Excellent inter-rater reliability was seen on all four of these global ratings. It appears, therefore, that even without specific subscales, the MAGIC can provide reliable estimates of both general psychotherapeutic and specific CBT skills. The global ratings were made after live scoring of the individual items, and on to the same scoring sheet, so we assume that the global ratings were informed by the detailed information acquired during the session. (That is, the same level of inter-rater agreement may not have been reached if observers were making their own notes rather than using the same standard instrument.)

The data collected using the MAGIC demonstrate that the processes that underpin the adaptation of group therapy for people with intellectual disabilities can be reliably recorded. Although constructs to emerge most strongly from the factor analysis, such as 'communication', 'respect', and 'empathy', are clearly relevant to psychotherapeutic interventions with any group, issues such as the pacing of sessions and pitching communication at the right level are particularly pertinent therapeutic judgements when working with people who have intellectual disabilities.[67,143] Thus, the analysis seems to provide some support for the face validity of the instrument with this client group. The validity of the MAGIC is supported by its ability to predict two key outcomes of the intervention: anger ratings and the acquisition of anger coping skills. (We note, however, that higher fidelity was associated with both better acquisition of coping skills, as predicted, and higher anger ratings, which is the inverse of the predicted relationship. This has implications for the interpretation of PI scores, which will be discussed in *Chapter 10*.) The validity of the MAGIC is also supported by the significant relationship between fidelity and predictions of clinical outcome, which were made on the basis of knowledge acquired through supervision of the lay therapists but without any direct contact with the groups.

Utility

With regard to the delivery of the anger management manual by the lay therapists, it is noteworthy that the levels of fidelity recorded were reasonably good, and consistent across two separate waves of data collection. Indeed, our ratings of the lay therapists, whose training comprised a single day of instruction followed up by fortnightly supervision, compared favourably with those reported by Haddock *et al.*[66] for the CTS-Psy. In their study, only 8 of 14 psychotherapy trainees scored above 50% compared with our mean overall score of 64%. The difference could result either from the fewer items in the MAGIC ($n = 30$) as compared with the CTS-Psy ($n = 60$), with the possibility that we selected items that are easier to achieve, or more likely, from the use in the present study of a prescriptive manual containing detailed session plans. In a classic study, Strupp and Hadley[144] reported that there was no difference between psychotherapeutic outcomes between experienced psychotherapists and therapeutically naive 'college professors chosen for their ability to form understanding relationships'. Although our 'lay therapists' had no prior training or experience in CBT, the ability to form understanding relationships is the principal requirement for selection to their employment as support workers for people with intellectual disabilities, and this ability is likely to contribute to their high scores on the fidelity monitoring checklist.

As might be expected, groups varied in the fidelity ratings achieved. However, there did appear to be particular strengths in the delivery of the manual, with activities usually carried out and materials used appropriately. Moreover, therapists also demonstrated the desired communication and group skills in the majority of instances, suggesting that most lay therapists were able to communicate the ideas contained in the manual effectively. The weakest components were in relation to specific CBT skills. These included a number of specific techniques that were not delivered because they had not been explicitly emphasised in the manual, but, also, most of the more abstract CBT elements, concerned with the service users' thoughts and feelings. It might be argued that delivering CBT requires therapists to have grounding in relevant theory and a particular set of therapeutic skills,[145] making it unsurprising that these elements were largely absent. However, a further reason for the lower scores regarding these CBT components of the intervention might have been that service users struggled to grasp the relevant concepts. Clearly, fidelity instruments such as MAGIC are meant to assess how faithful the therapists remain to the content and spirit of the approach set out in the manual. However, it may also be necessary to take account of the service users' intellectual difficulties when interpreting the fidelity ratings.

A number of limitations of this study can be identified. First, some minor changes were made to the guidance provided to monitors during the course of the study. However, results obtained in the second wave of data collection were very similar to those obtained previously, so it appears that this had little effect on the overall picture. Second, these changes arose out of difficulties identified in identifying some items as 'absent'. Considering the high overall fidelity scores recorded, it must be considered that the criteria used to decide that an item was present may have been too generous. Against this, we note that there was considerable variability in overall scores across groups, with one set of 'lay therapists' achieving a very poor score. Finally, the MAGIC has not yet been used outside the context of the present manualised intervention for anger. Although we consider that the reliability of the instrument would probably be retained in other therapeutic contexts, it might be lower for interventions with a less prescriptive manual.

One of the reasons that it has been difficult to carry out intervention studies with people who have intellectual disabilities has been a lack of reliable and validated assessments. This applies as much to fidelity measures as to other domains, such as self-report measures of distress.[146] The heterogeneity of people with intellectual disabilities, in terms of communicative and intellectual abilities, is also thought to be a barrier to the development of manualised interventions. However, the present use of the MAGIC has shown that it is possible not only to develop a manual that can be used flexibly to address the particular needs of group members but also to record reliably whether or not the intervention is delivered in a sensitive fashion and whether or not therapists can successfully engage group members in the sessions, as well as identifying individual strengths and weaknesses. The MAGIC items were deliberately worded in a non-specific manner, so that the instrument could be used in other therapeutic contexts, and we would hope that the degree of reliability that we observed would be retained. Therefore, the development of this fidelity measure may play a role in facilitating intervention studies with people who have intellectual disabilities, and increasing the evidence base in relation to group-based CBT interventions.

Chapter 6 Results: clinical outcomes

Primary outcome: self-reported Provocation Index at the 10-month follow-up

On the primary outcome, self-reported PI scores at the 10-month follow-up (all cases), scores were a little lower in the intervention group than in control subjects but the effect was not statistically significant (*Table 38*).

A CACE analysis was run on data from service users who attended at least eight group sessions ($n = 63$), and the same proportion of controls ($n = 62$). The intervention effect on self-rated 10-month PI scores was slightly larger than in the main analysis but remained non-significant ($p = 0.165$).

The results for individual groups are shown in *Figure 3*. Most of the control groups showed increases in self-reported PI scores at the 10-month follow-up compared with baseline. In three earlier studies there was a mean 14-point decrease in PI scores from baseline to follow-up 3–6-months post intervention.[11,39,48] One of the intervention groups (#206) had a large decrease in PI, similar to the effects reported in earlier studies, with six others showing more modest effects; however, PI increased in some groups.

Other anger outcomes

Self-reported Provocation Index at 16-week follow-up

At the 16-week follow-up, the difference in PI scores was larger than at 10 months and approached, but again did not reach, statistical significance ($p = 0.083$) (*Table 39*). These results reflect a tendency for PI scores to increase in control subjects and to decrease in the intervention group (*Figure 4a*).

As with the 10-month outcome, when the analysis was adjusted to include only intervention-compliant participants (CACE analysis) the intervention effect increased but still failed to reach significance ($p = 0.063$).

Key worker-reported Provocation Index

Key workers reported larger decreases in service users' anger, relative to the control group, than was reported by service users (*Table 40*). The decrease in PI scores, as reported by key workers, was not quite significant at the 16 week follow-up but was significant at the 10-month follow-up. Again, these results

TABLE 38 Self-reported PI at 10 months

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference: Lower bound	95% CI for adjusted mean difference: Upper bound	ICC[c]	*p*-value
PI	143 (72, 71)	45.1 (17.46)	41.4 (23.78)	2.8	–1.7	7.4	0.005	0.210

SD, standard deviation.
a Standard deviation inflated for centre-level clustering.
b Difference calculated as: control – intervention.
c Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

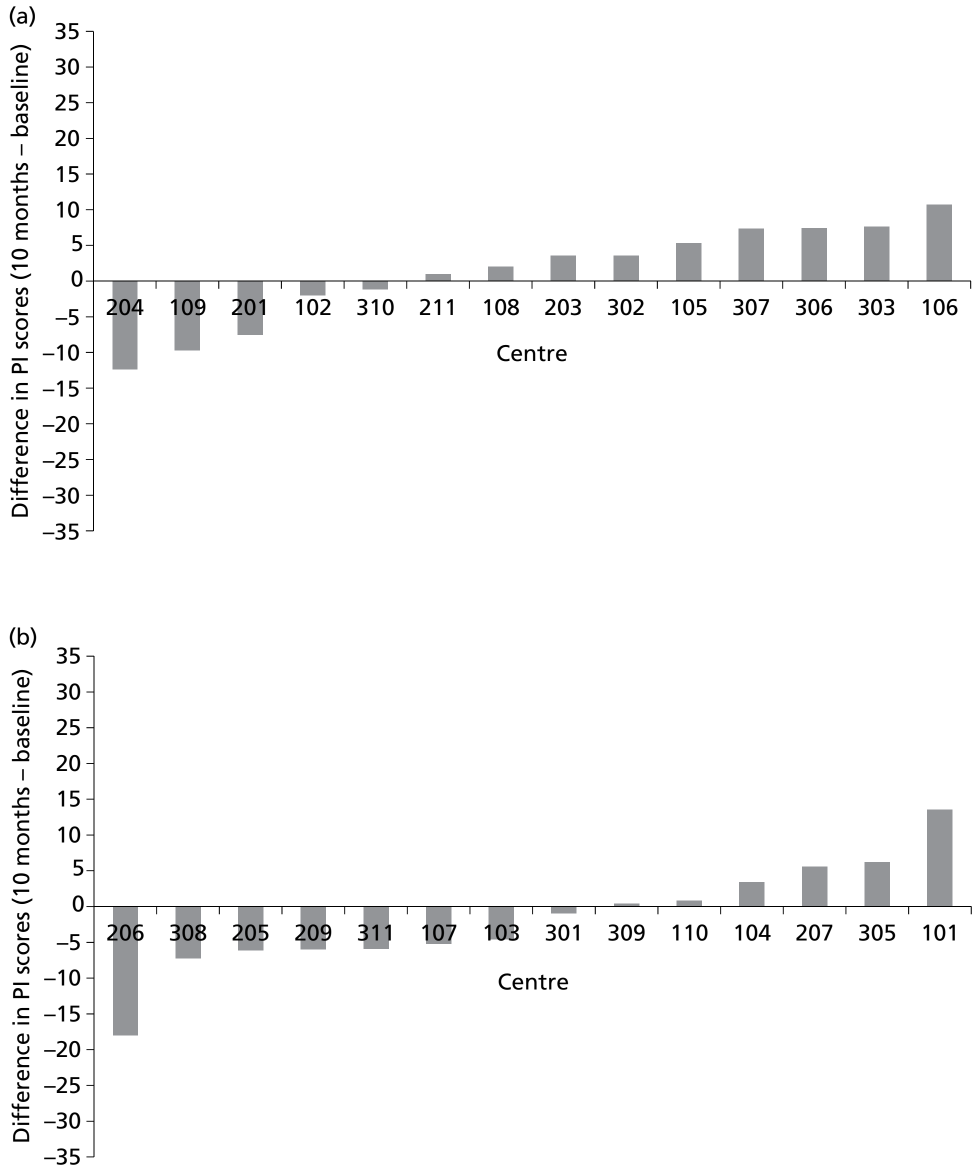


FIGURE 3 Centre differences in self-reported PI at 10 months. Difference between the 10-month follow-up and baseline PI scores in control group centres (a) and intervention group centres (b).

TABLE 39 Self-reported PI at 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference: Lower bound	95% CI for adjusted mean difference: Upper bound	ICC[c]	*p*-value
PI	162 (85, 77)	47.8 (14.81)	41.5 (29.15)	4.4	–0.6	9.4	0.124	0.083

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Difference calculated as: control – intervention.

c Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

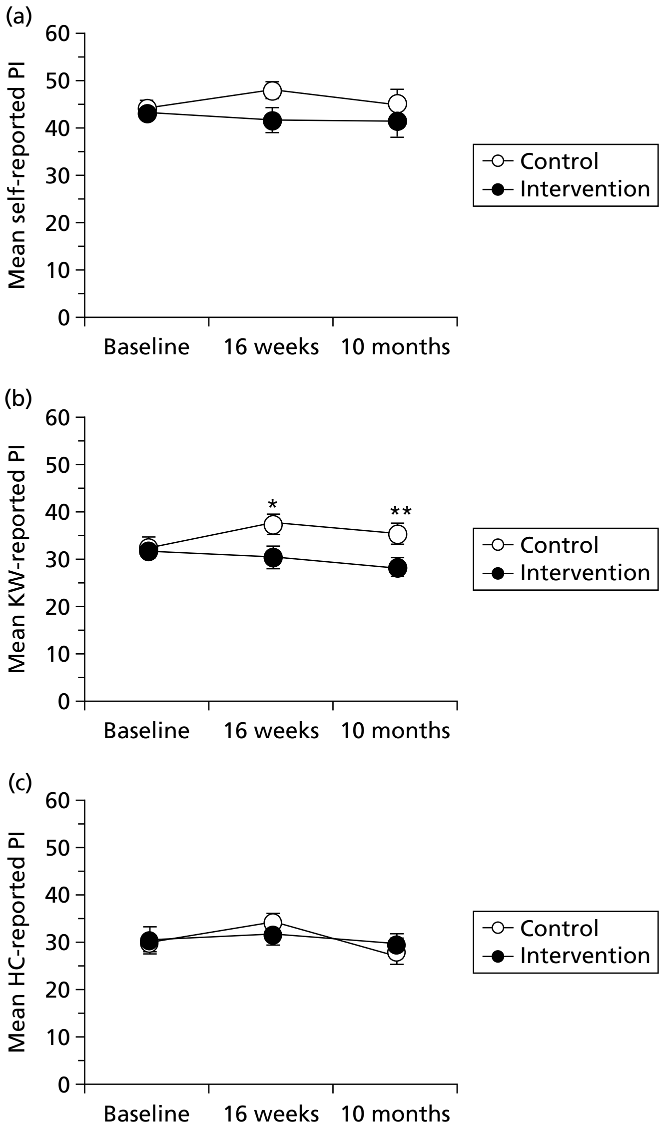


FIGURE 4 Comparison of self-reported (a), key worker-reported (b) and home carer-reported (c) PI scores between control and intervention at baseline, 16 weeks and 10 months. HC, home carer; KW, key worker. **p*<0.05; ***p*<0.01; ****p*<0.001.

TABLE 40 Key worker-reported PI at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference		ICC[c]	*p*-value
					Lower bound	Upper bound		
PI at 16 weeks	161 (82, 79)	37.7 (19.73)	30.8 (20.31)	6.1	–0.3	12.5	0.276	0.060
PI at 10 months	150 (73, 77)	35.7 (21.55)	28.6 (17.26)	6.3	0.9	11.6	0.103	0.023

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Difference calculated as: control – intervention.

c Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

reflect both increased scores in the control subjects and decreased scores in the participants receiving the intervention (*Figure 4b*). The adjustment of the analysis for those participants who were compliant with the intervention (CACE analysis) increased the effect sizes, which were significant at both time points (16 weeks, $p<0.05$; 10 months, $p<0.01$).

It had been intended that, if key workers also acted as lay therapists, another staff member who knew the service user well would provide the key worker information. However, in some cases this was not possible, particularly for the follow-up assessments. In these cases, lay therapists provided key worker information. This represents a potential source of bias, as lay therapists might exaggerate the gains made by service users in their group. In order to evaluate this potential source of bias, the key worker analyses were repeated after excluding any reports from key workers who were also lay therapists. A total of 14 key worker reports in the intervention group were excluded for this reason. Contrary to expectations, the effects of the intervention actually increased slightly after excluding these reports (16 weeks, $p<0.05$; 10 months, $p<0.025$) (*Table 41*).

The results for individual groups are shown in *Figure 5*. The control groups showed an increase or a very small decrease in key worker-rated PI scores. In three earlier studies there was a mean 13-point decrease in PI scores from baseline to follow-up 3–6-months post intervention.[11,39,48] The intervention groups showed decreases or very small increases in key worker-rated PI scores, with three groups (#207, #308 and #209) showing decreases that were similar to those previously reported.

Home carer-reported Provocation Index

Home carers did not report significant decreases in service users' anger (*Table 42* and *Figure 4c*). The effects of adjusting the analysis to exclude non-compliant participants were negligible.

Self-reported Profile of Anger Coping Skills anger ratings

A further source of information about service users' anger comes from the PACS-IPT. An exploratory post hoc analysis of these data was undertaken as a potential means of understanding better the unexpected lack of a significant effect of the intervention on service user PI scores, which was discrepant from both key worker PI ratings (see *Figure 4*) and the published literature (see *Table 2*).

Service users' mean ratings on the PI were just under 60% of maximum at baseline, and, as reported earlier, little change was seen at follow-up. PACS-IPT ratings were much higher at baseline (85% maximum), which was expected, given that the scenarios included in the PACS represented situations that triggered anger for the individual participant. PI and PACS-IPT ratings are compared in *Figure 6*. In contrast with the lack of change in PI scores, PACS-IPT ratings decreased significantly in the intervention group at the 16-week follow-up ($p<0.01$), and the difference between intervention and control groups was maintained at the 10-month follow-up ($p<0.05$) (*Table 43*).

TABLE 41 Key worker-reported PI at 10 months and 16 weeks, excluding reports from those who also acted as lay therapists

	With lay therapist key worker reports excluded:				
			95% CI		
Outcome	Total *N* (*n* control, *n* intervention)	Adjusted mean difference[a,b]	Lower bound	Upper bound	*p*-value
PI at 16 weeks	147 (82, 65)	7.3	0.7	13.9	0.032
PI at 10 months	136 (73, 63)	6.9	1.1	12.7	0.021

a Difference calculated as: control – intervention.

b Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

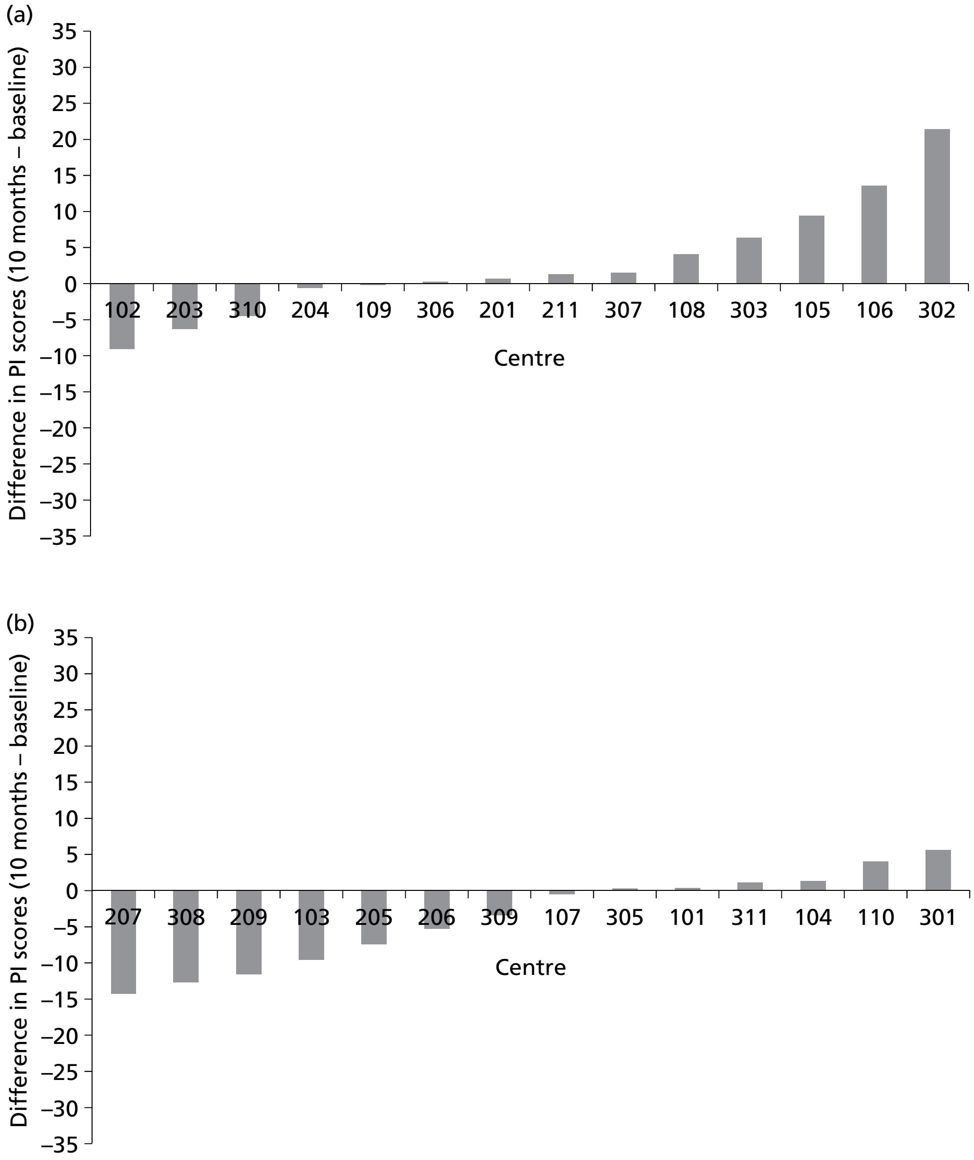


FIGURE 5 Centre differences in key worker-reported PI at 10 months. Difference between 10-month follow-up and baseline key worker PI scores in control group centres (a) and intervention group centres (b).

TABLE 42 Home carer-reported PI at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference Lower bound	95% CI for adjusted mean difference Upper bound	ICC[c]	*p*-value
PI at 16 weeks	104 (59, 45)	34.0 (16.45)	31.4 (14.60)	1.9	–2.5	6.2	0.005	0.372
PI at 10 months	84 (41, 43)	27.8 (17.61)	29.3 (15.86)	0.3	–6.6	7.1	0.000	0.940

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Difference calculated as: control – intervention.

c Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

Data expressed as per cent of maximum score.

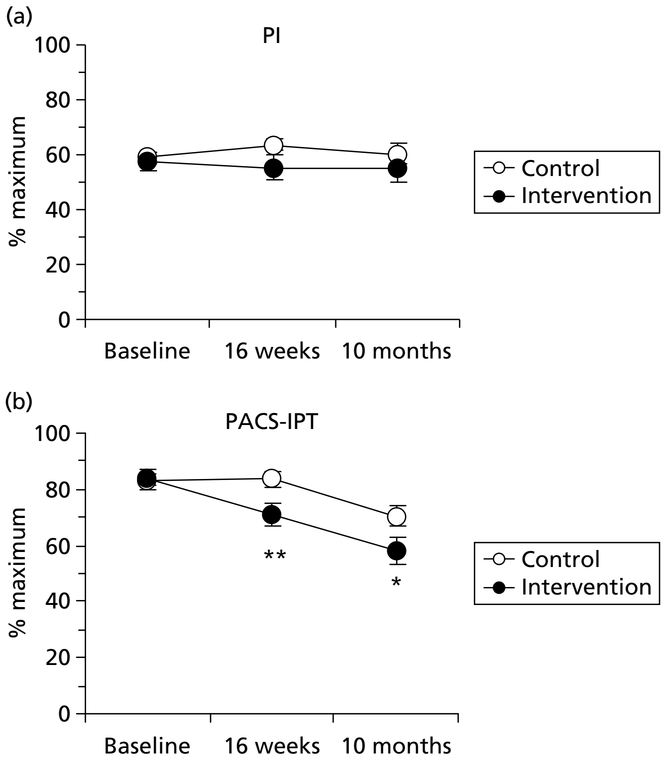


FIGURE 6 A comparison of PI (a) and PACS-IPT (b). $*p<0.05$; $**p<0.01$; $***p<0.001$, based on ranked analysis of covariance, controlling for baseline PACS-IPT.

TABLE 43 Self-reported PACS anger ratings

	Baseline		16-week follow-up		10-month follow-up	
PACS-IPT median[a]	Control: % (*n*)	Intervention: % (*n*)	Control: % (*n*)	Intervention: % (*n*)	Control: % (*n*)	Intervention: % (*n*)
0–0.5	3.6 (3)	3.4 (3)	3.7 (3)	18.7 (14)	12.1 (8)	29.6 (21)
1–1.5	31.0 (26)	25.9 (23)	28.1 (23)	26.4 (20)	42.4 (28)	29.6 (21)
2	65.5 (55)	70.8 (63)	68.3 (56)	55.3 (42)	45.5 (30)	40.8 (29)
Total	*100.0 (84)*	*100.0 (89)*	*100.0 (82)*	*100.0 (76)*	*100.0 (66)*	*100.0 (71)*

[a] Median rating taken for up to three scenarios at the indicated time point. Ratings range from 0 (not angry) to 2 (very angry).

Anger coping

Self-reported Profile of Anger Coping Skills

In contrast to the small changes in self-reported anger, service users reported large and highly significant increases in use of anger coping skills (*Table 44*). The intervention and control groups differed significantly at 16 weeks ($p<0.001$), and this difference was maintained at the 10-month follow-up ($p<0.01$; see *Figure 7a*). At the 16-week follow-up, PACS ratings of service users in the intervention group were significantly aligned to key worker reports ($\rho=0.27$, $p<0.05$), but remained non-significant in the control group ($\rho=0.12$, non-significant).

TABLE 44 Self-reported PACS at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference		ICC[c]	*p*-value
					Lower bound	Upper bound		
PACS at 16 weeks	156 (82, 74)	29.2 (24.00)	37.9 (25.04)	–11.3	–17.7	–4.9	0.129	0.001
PACS at 10 months	138 (67, 71)	26.4 (23.24)	34.1 (27.19)	–9.7	–16.8	–2.6	0.139	0.010

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Difference calculated as: control – intervention.

c Adjustments made for clustering at centre-level and baseline score in a two-level ANCOVA model.

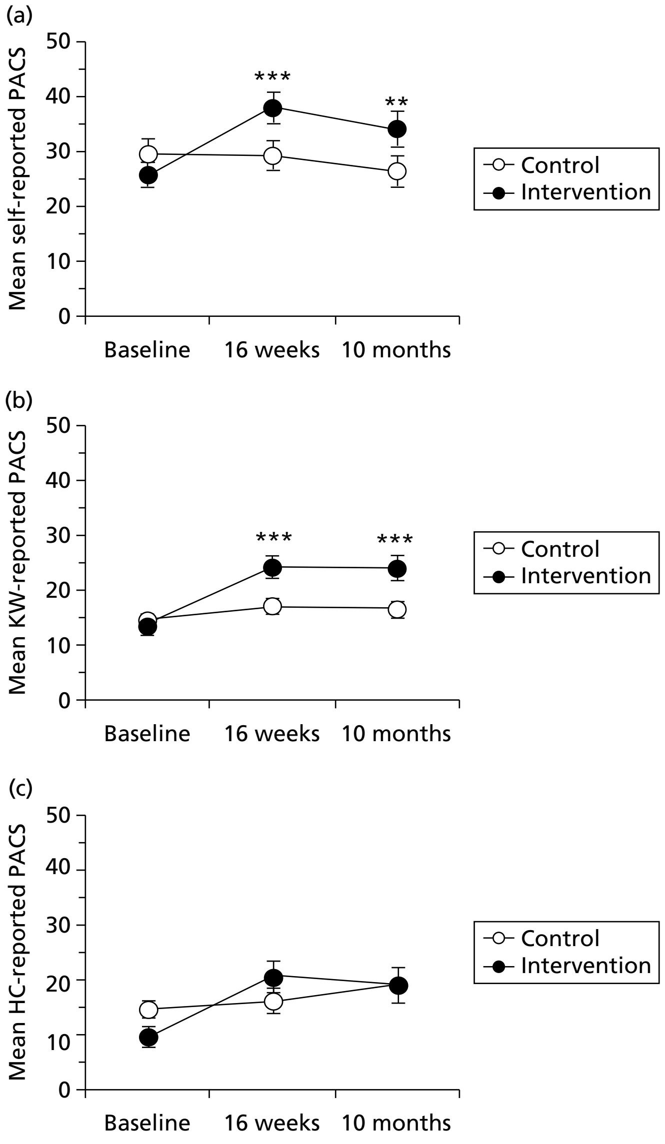


FIGURE 7 Comparison of self-reported (a), key worker-reported (b) and home carer-reported (c) PACS scores between control and intervention at baseline, 16 weeks and 10 months. HC, home carer; KW, key worker. *$p<0.05$; **$p<0.01$; ***$p<0.001$.

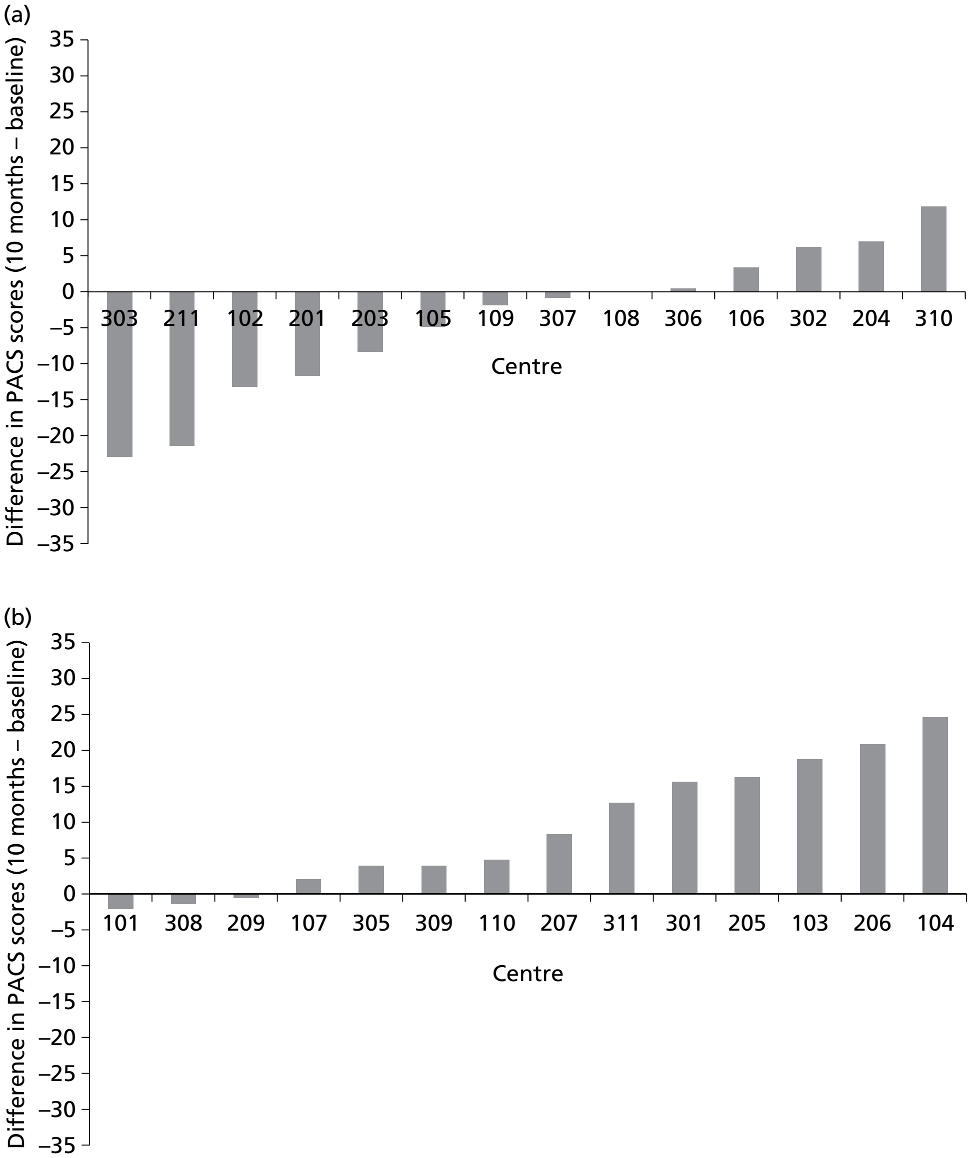


FIGURE 8 Centre differences in self-reported PACS at 10 months. Difference between 10-month follow-up and baseline PACS scores in control group centres (a) and intervention group centres (b).

The results for individual groups are shown in *Figure 8*. Most of the control groups reported poorer coping at the 10-month follow-up compared with baseline. Six of the intervention groups (#104, #206, #103, #205, #301, #311) had a large increases in PACS scores that were similar to or greater than the effects reported by key workers in earlier studies,[11,48] with four others showing more modest effects and minimal change in the other four groups.

Key worker-reported Profile of Anger Coping Skills

Key workers also reported large improvements in the use of anger coping skills, at both the 16-week ($p<0.002$) and the 10-month ($p<0.01$) follow-up assessments (*Table 45* and *Figure 7b*). The proportional increase in PACS scores as reported by key workers was substantially larger than service users' self-reports. This reflects the fact that key worker ratings of anger coping were lower at baseline than service users' self-reports (as reported in *Chapter 3*): the effect of the intervention in absolute terms was similar in size in self-reports and key worker reports. The estimates in *Table 45* correspond to adjusted mean differences on the original scale of 8 at 16 weeks and 9 at 10 months.

In order to evaluate the potential bias arising from the inclusion of key workers who were also lay therapists, the analyses were repeated after excluding reports from these participants. As with the PI, the changes in key worker PACS ratings remained significant in both the 16-week ($p < 0.005$) and the 10-month ($p < 0.025$) follow-up assessments (*Table 46*).

The results for individual groups are shown in *Figure 9*. Most of the control groups reported poorer coping at the 10-month follow-up than at baseline. In two previous studies there was a mean 13-point increase in PACS scores from baseline to follow-up 3–6 months post intervention.[11,48] The intervention groups all showed an increase in key worker-rated PACS scores, with the increases in the best six groups (#311, #103, #107, #104, #209, #205) similar to those reported earlier. The rank ordering of groups was similar for service user and key worker PACS ratings ($\rho = 0.54$, $p = 0.05$).

Home carer-reported Profile of Anger Coping Skills

The PACS scores as reported by home carers improved in the intervention group in both follow-up assessments, but the differences from controls were much smaller than reported by service users and key workers and non-significant (*Table 47* and *Figure 7c*).

TABLE 45 Key worker-reported PACS at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference: Lower bound	95% CI for adjusted mean difference: Upper bound	ICC[b]	*p*-value
PACS at 16 weeks[d]	157 (81, 76)	17.1 (12.24)	24.1 (18.35)	–1.0	–1.6	–0.4	0.100	0.002
PACS at 10 months[d]	140 (70, 70)	16.5 (13.41)	23.9 (19.18)	–0.9	–1.6	–0.3	0.113	0.006

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

c Difference calculated as: control – intervention.

d Adjusted mean difference and 95% CI on transformed scale.

TABLE 46 Key worker-reported PACS at 10 months and 16 weeks, excluding reports from those who also acted as lay therapists

	With lay therapist key worker reports excluded:				
			95% CI		
Outcome	Total *N* (*n* control, *n* intervention)	Adjusted mean difference[a–c]	Lower bound	Upper bound	*p*-value
PACS at 16 weeks[a]	146 (81, 65)	–0.9	–1.5	–0.3	0.003
PACS at 10 months[a]	128 (70, 58)	–0.8	–1.4	–0.1	0.021

a Adjusted mean difference and 95% CI on transformed scale.

b Difference calculated as: control – intervention.

c Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

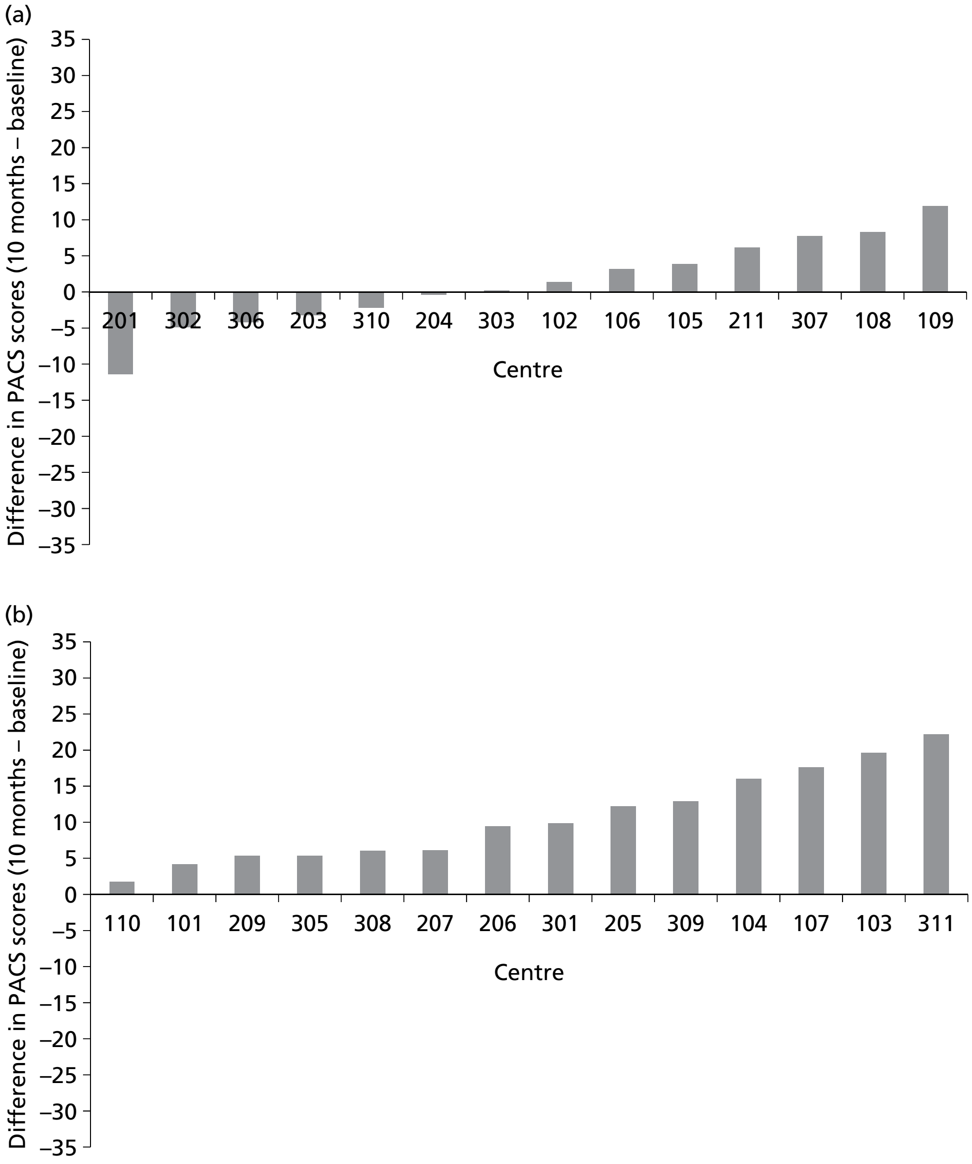


FIGURE 9 Centre differences in key worker-reported PACS at 10 months. Difference between 10-month follow-up and baseline key worker PACS scores in control group centres (a) and intervention group centres (b).

Anger coping in treatment-compliant participants

The exclusion of non-compliant participants (CACE analyses) increased the effect size for anger coping in all analyses. This had the effect of increasing the significance level for service users at 10 months ($p < 0.005$) and for key workers at both time points ($p < 0.001$). Home carer ratings remained non-significant.

Mental health

Service users' self-reports on the four mental health measures are shown in *Table 48*. No significant effects were found at either 16-week or 10-month follow-up assessments. On all measures, restricting the analysis to treatment-compliant participants (CACE analysis) led to slightly larger effects and slightly smaller p-values, but none of the effects at either time point approached statistical significance (minimum $p = 0.122$).

TABLE 47 Home carer-reported PACS at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference		ICC[b]	*p*-value
					Lower bound	Upper bound		
PACS at 16 weeks[d]	103 (58, 45)	16.1 (17.69)	20.4 (19.24)	–0.5	–1.5	0.6	0.256	0.356
PACS at 10 months[d]	85 (42, 43)	19.0 (21.53)	19.0 (20.90)	–1.5	–11.5	8.5	0.166	0.749

SD, standard deviation.
a Standard deviation inflated for centre-level clustering.
b Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.
c Difference calculated as: control – intervention.
d Adjusted mean difference and 95% CI on transformed scale.

TABLE 48 Self-reported mental health measures at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference		ICC[b]	*p*-value
					Lower bound	Upper bound		
At 16 weeks								
GDS[d]	157 (81, 76)	9.8 (6.76)	9.1 (8.20)	0.2	–0.1	0.5	0.003	0.150
GAS	154 (79, 75)	18.3 (8.74)	16.0 (10.70)	1.6	–0.7	3.9	0.011	0.169
RSES[d]	141 (74, 67)	25.0 (3.86)	25.3 (3.90)	0.1	–0.2	0.3	0.000	0.514
COMQoL[d]	129 (67, 62)	99.9 (31.34)	94.3 (40.22)	6.8	–4.8	18.3	0.000	0.249
At 10 months								
GDS[d]	144 (72, 72)	8.1 (5.99)	8.3 (8.24)	0.1	–0.3	0.5	0.057	0.623
GAS	143 (71, 72)	15.2 (8.94)	15.6 (9.29)	–0.5	–3.0	1.9	0.000	0.677
RSES[d]	134 (70, 64)	26.5 (4.12)	25.8 (4.81)	31.8	–39.2	102.9	0.069	0.362
COMQoL[d]	140 (70, 70)	98.1 (41.94)	97.5 (34.09)	839.2	–2506.1	4184.5	0.000	0.621

SD, standard deviation.
a Standard deviation inflated for centre-level clustering.
b Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.
c Difference calculated as: control – intervention.
d Adjusted mean difference and 95% CI on transformed scale.

Challenging behaviour

Key worker reports

Key workers reported significant improvements, relative to control subjects, at the 16-week follow-up, on two measures of challenging behaviour: the ABC-H ($p < 0.001$) and ABC-I ($p < 0.005$) (*Table 49* and *Figure 10a* and c). As with PI scores (see *Figure 4*), the changes reflect a tendency for ABC scores to decrease in the intervention group and increase in the control group, and as with PI scores, these changes

TABLE 49 Key worker-reported challenging behaviour measures at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference: Lower bound	Upper bound	ICC[b]	*p*-value
At 16 weeks								
ABC-H[d]	159 (81, 78)	12.7 (10.20)	7.9 (7.71)	0.7	0.3	1.1	0.058	0.001
ABC-I[d]	158 (81, 77)	11.0 (9.53)	7.5 (7.82)	0.7	0.2	1.1	0.184	0.005
MOAS[d]	158 (82, 76)	8.3 (12.18)	10.0 (14.80)	–0.1	–0.9	0.8	0.263	0.914
CBS	158 (81, 77)	46.1 (11.22)	47.4 (8.66)	–0.7	–3.3	1.9	0.104	0.572
At 10 months								
ABC-H[d]	150 (73, 77)	9.4 (8.97)	8.2 (8.39)	0.3	–0.2	0.7	0.116	0.263
ABC-I[d]	150 (73, 77)	7.6 (6.81)	8.4 (9.80)	0.1	–0.3	0.6	0.095	0.561
MOAS[d]	140 (66, 74)	5.2 (12.10)	5.6 (12.15)	0.1	–0.7	0.8	0.174	0.818
CBS	147 (73, 74)	47.7 (10.59)	46.8 (11.09)	0.6	–2.4	3.7	0.140	0.673

SD, standard deviation.

a Standard deviation inflated for centre-level clustering.

b Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

c Difference calculated as: control – intervention.

d Adjusted mean difference and 95% CI on transformed scale.

increased slightly after excluding reports from key workers who also acted as lay therapists (ABC-H, $p < 0.002$; ABC-I, $p < 0.005$). As with other measures, the exclusion of non-compliant participants (CACE analysis) slightly increased the effect size ($p < 0.001$ for both measures).

The improvements in challenging behaviour reported at 16 weeks were not maintained at the 10-month follow-up. However, this largely reflects changes in ABC scores in the control group, rather than an increase in challenging behaviour by participants who received the intervention.

Figure 10e shows the proportion of service users in each group who met the criterion for severe challenging behaviour, which decreased by 23% in the intervention group at 16 weeks and remained at a similar level at 10 months. There was no change in the control group at 16 weeks, followed by a spontaneous decrease at 10 months.

No significant effects were reported for the MOAS. Neither did key workers' attributions of challenging behaviour, as reported by the CBS, change significantly (see *Table 50*).

Home carer reports

Home carers also reported improvements in challenging behaviour, relative to the control group, at the 16-week follow-up, as measured by the ABC-H ($p < 0.05$). A similar pattern of results was seen on the ABC-I, albeit these changes were not statistically significant (*Table 50* and *Figure 10b* and *d*). The significance of effect of the intervention on the ABC-H was lost at the 10-month follow-up, but challenging behaviour continued to decrease on both measures. Effect sizes increased marginally when non-compliant participants were excluded (CACE analysis). No change was seen on the MOAS.

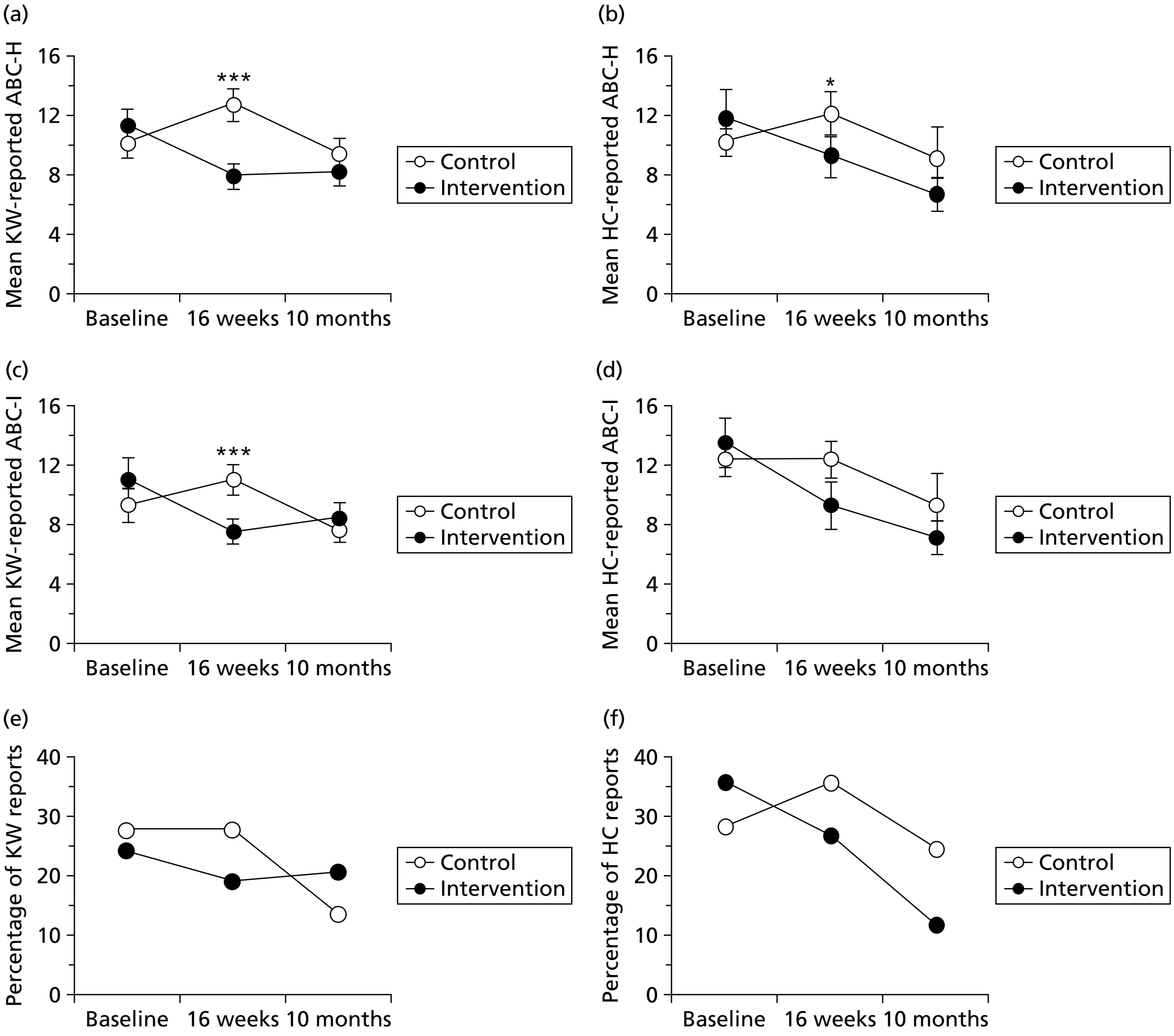


FIGURE 10 Comparison of key worker-reported (a, c and e) and home carer-reported (b, d and f) ABC scores between control and intervention at baseline, 16 weeks and 10 months. (a) Key worker-reported ABC-H; (b) home carer-reported ABC-H; (c) key worker-reported ABC-I; (d) home carer-reported ABC-1; (e) key worker % severe challenging behaviour; (f) home carer % severe challenging behaviour. HC, home carer; KW, key worker. *$p<0.05$; **$p<0.01$; ***$p<0.001$.

Figure 10f shows the proportion of service users in each group who met the criterion for severe challenging behaviour, which decreased by 25% at 16 weeks, with a further decrease to 32% of the baseline value at 10 months. In the control group the proportion showing severe challenging behaviour increased at 16 weeks, followed by a return to 87% of the baseline value at 10 months.

Complier-adjusted causal effect analysis

The compliance ICC (the level of cluster within centres in whether or not a service user was compliant) was calculated as 0.38. However, in terms of outcomes, compliers and non-compliers were not substantially different from each other. We would, therefore, not expect the clustering of compliance to contribute to the misestimation of variance in our CACE estimates, despite this clustering being considerable.

TABLE 50 Home carer-reported challenging behaviour measures at 10 months and 16 weeks

Outcome	Total *N* (*n* control, *n* intervention)	Control mean (SD)[a]	Intervention mean (SD)[a]	Adjusted mean difference[b,c]	95% CI for adjusted mean difference		ICC[b]	*p*-value
					Lower bound	Upper bound		
At 16 weeks								
ABC-H[d]	104 (59, 45)	12.1 (12.01)	9.3 (9.69)	0.5	0.0	1.1	0.060	0.046
ABC-I[d]	104 (59, 45)	12.4 (9.57)	9.3 (10.85)	0.4	–0.2	1.1	0.154	0.187
MOAS[d]	103 (58, 45)	12.7 (14.67)	8.7 (18.31)	0.4	–0.8	1.4	0.275	0.520
At 10 months								
ABC-H[d]	84 (41, 43)	9.1 (13.84)	6.7 (7.57)	0.3	–0.4	1.1	0.000	0.370
ABC-I[d]	84 (41, 43)	9.3 (13.50)	7.1 (7.48)	0.2	–0.6	1.0	0.000	0.577
MOAS[d]	83 (41, 42)	7.0 (15.90)	6.5 (13.80)	–0.7	–12.2	10.8	0.000	0.903

SD, standard deviation.

[a] Standard deviation inflated for centre-level clustering.

[b] Adjustments made for clustering at centre level and baseline score in a two-level ANCOVA model.

[c] Difference calculated as: control – intervention.

[d] Adjusted mean difference and 95% CI on transformed scale.

Secondary analyses

Secondary analyses of primary outcome

Effect of region and service type

In order to determine whether or not the impact of the intervention on the primary outcome differed across regions (Scotland, England and Wales), the primary model was refitted with a region by trial group interaction term, based on 143 service users (complete cases) nested within 28 centres. The main effects of region and the interaction terms were all non-significant ($p > 0.19$), indicating that the effect of the intervention on self-reported PI scores at the 10-month follow-up did not differ significantly between regions.

The effect of service type (local authority/other) was examined by fitting an interaction term to the primary model, based on 143 service users (complete cases) nested within 28 centres. The main effects of service type and the interaction term were both non-significant (p 0.17), indicating that the effect of the intervention on self-reported PI scores at the 10-month follow-up did not differ significantly between local authority and non-local authority services.

Control for variables balanced/minimised at randomisation

We chose to minimise/balance on two variables at baseline (exposure to therapists outside of sessions and baseline PI score), as these might have confounded the relationship between the intervention and the primary outcome. In order to determine what impact these variables had, the primary model was refitted with interaction terms (individual-level exposure × trial group and individual-level baseline PI × trial group) based on 143 service users (complete cases) nested within 28 centres. Both of the interaction terms were non-significant ($p \geq 0.55$), indicating that the effect of the intervention on self-reported PI scores at the 10-month follow-up was not significantly influenced by either of these variables.

Diagnosis of learning disability

A planned subgroup analysis was conducted to examine whether or not the outcome at the 10-month follow-up was different in service users ($n = 157$) who met the IQ criterion for a diagnosis of learning disability (FSIQ <70) and those who did not ($n = 17$). The primary model was refitted with an interaction term including a dichotomised IQ variable, based on 136 service users nested within 28 centres. The main effect and interaction were both non-significant ($p \geq 0.58$), indicating that the effect of the intervention on self-reported PI scores at the 10-month follow-up was not significantly different in participants with and without a formal diagnosis of learning disability. This does not necessarily imply that there was no relationship between IQ and outcome among those who did meet the criterion for a diagnosis of learning disability. We return to this question in *Chapter 9*.

Acknowledgement of anger problems

A second planned subgroup analysis was conducted in which we reran the primary analysis excluding those service users who did not acknowledge experiencing significant anger problems, defined as a baseline self-reported PI score of at least 25, corresponding to a mean item score of 1.0. This analysis was based on 120 service users nested within 27 centres. The exclusion of very low baseline PI scores led to a 12% increase in the effect of the intervention at the 10-month follow-up (adjusted difference between groups: all service users, 2.89; excluding PI$<$25, 3.33), but the effect remained non-significant ($p = 0.215$).

Influence of baseline mental health status

A further planned analysis was conducted to examine whether or not the outcome at the 10-month follow-up was influenced by participants' baseline mental health status. The primary analysis was extended by including baseline mental health scores (GDS, GAS and RSES) as covariates and interacting them with trial group. All three interaction terms were non-significant ($p \geq 0.19$), indicating that mental health state at baseline did not significantly influence the effect of the intervention on self-reported PI scores at the 10-month follow-up.

Secondary analyses of Profile of Anger Coping Skills outcome

Some secondary analyses were also conducted on the key secondary variable of anger coping at the 10-month follow-up assessment.

Diagnosis of learning disability

We first examined whether or not self-reported PACS scores at the 10-month follow-up were different in service users ($n = 157$) who met the IQ criterion for a diagnosis of learning disability (FSIQ <70) and those who did not ($n = 17$). As was done for PI scores, the primary model was refitted with an interaction term including a dichotomised IQ variable, based on 127 service users (complete cases) nested within 28 centres. The effect of the intervention remained significant ($p < 0.02$), but both the main effect of IQ$<$70 and the interaction term were non-significant ($p \geq 0.20$), indicating that participants who met the criterion for a diagnosis of learning disability did not differ significantly from those who did not in the effect of the intervention on PACS scores at the 10-month follow-up.

Influence of baseline mental health status

An exploratory analysis was conducted to examine whether or not the outcome at the 10-month follow-up was influenced by participants' baseline mental health status. As was done for PI scores, the primary analysis was extended by including baseline mental health scores (GDS, GAS and RSES) as covariates and interacting them with trial group, based on 128 service users (complete cases) nested within 28 centres. Both the main effect and interaction term were non-significant for RSES scores ($p \geq 0.67$). For GDS scores, the main effect was significant ($p < 0.01$) but the interaction was not ($p = 0.46$), indicating that participants who were more depressed at baseline had a poorer prognosis at the 10-month follow-up, irrespective of trial group. However, for GAS scores the main effect and the interaction were both significant ($p < 0.01$ and $p < 0.05$, respectively). These effects are illustrated in *Figure 11*. For participants in the control group, higher levels of anxiety at baseline were associated with a poorer prognosis at the 10-month follow-up.

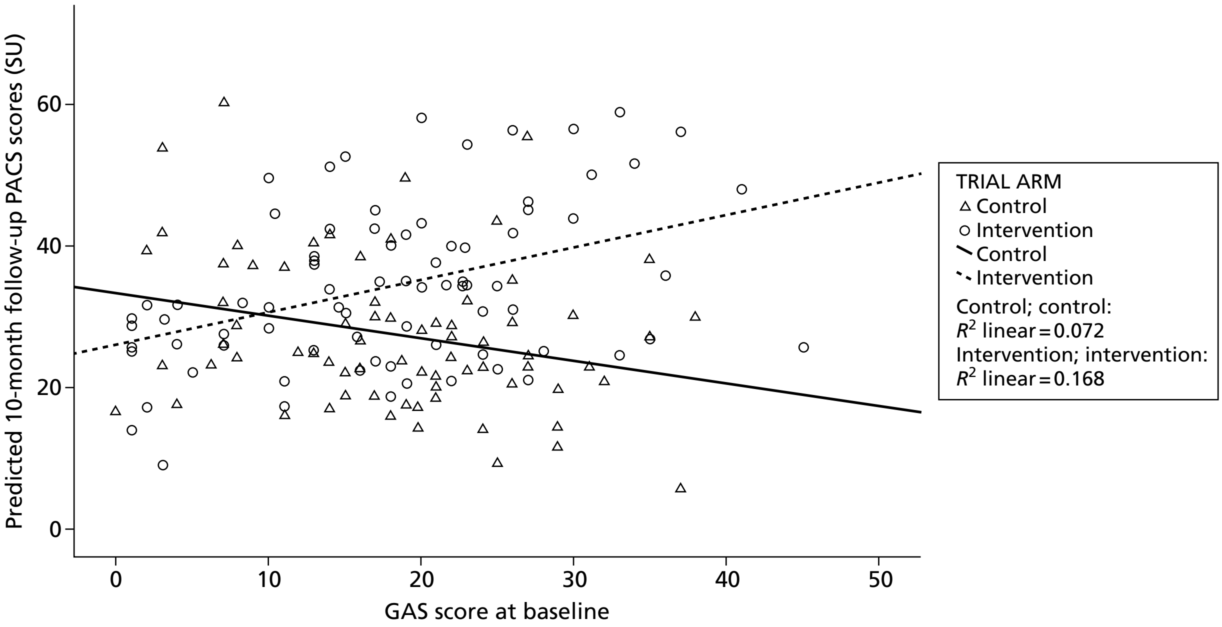


FIGURE 11 The GAS by trial arm interaction.

However, for participants in the intervention group, higher levels of anxiety at baseline were associated with greater benefit from the intervention.

Influence of type of service

A further exploratory analysis was conducted to examine whether or not the outcome at the 10-month follow-up was influenced by the type of service that participants attended. As was done for PI scores, the primary analysis was extended by including the type of service (local authority/non-local authority) as a covariate and interacting it with trial group. The main effect and interaction term were non-significant ($p \geq 0.46$), indicating that the effect of the intervention on self-reported PACS scores at the 10-month follow-up was not different between local authority and non-local authority services.

Stability of ratings across repeat assessments

For service users and key workers, there was a highly significant association between baseline and follow-up scores ($p < 0.001$) for all analyses conducted, suggesting that the characteristics assessed were relatively stable. For home carers, the associations between baseline and follow-up scores were significant ($p < 0.01$) at the 16-week follow-up, but were only marginally or non-significant at the 10-month follow-up (ABC-H, $p < 0.05$; all other variables, $p > 0.2$). This probably reflects the lower number of home carers at baseline, compounded by further attrition over time, as well as the fact that the respondent at the 10-month follow-up assessment was often different, particularly in the case of staff carers, who formed the majority.

Chapter 7 Impact on the costs of health and social care service use

Costs per week of health and social care resource use at baseline for the intervention and control groups are shown in *Table 51*. Overall costs for the intervention group were higher, with higher costs for daytime activities and community-based services contributing to slightly higher non-accommodation costs. The costs of staffed out-of-family accommodation were also higher for the intervention group despite fewer individuals in the intervention group being in such accommodation. The cost of domiciliary staff input received by members of the intervention group living independently, in adult family placements or in family homes was also higher.

Table 52 provides similar information at the 10-month follow-up. The sample size of the intervention and control groups had fallen by 20% and 22%, respectively. Non-accommodation costs for the intervention group were higher than those for control subjects, mainly due to higher costs of day activities. Categories other than psychotropic medication were also higher. However, staffed accommodation costs among this reduced sample were similar, with 29 service users in each group living in out-of-family staffed accommodation. The costs of domiciliary staff input and respite care received by members of the intervention group living independently in adult family placements, or in family homes, were higher than among the control subjects.

TABLE 51 Costs per person per week (£) of health and social care resource use at baseline for the intervention ($n = 84$) and control ($n = 85$) groups

	Intervention group ($n = 84$)		Control group ($n = 85$)	
Baseline: type of resource use	**Mean cost (£)**	**SD**	**Mean cost (£)**	**SD**
Non-accommodation costs				
Daytime activities	403.57	279.37	384.89	309.54
Psychotropic medication	2.54	8.46	2.79	10.21
Multidisciplinary meetings	12.17	31.22	10.17	25.80
Community-based services	43.00	84.90	28.41	53.21
Hospital-based services	7.60	42.08	9.09	64.78
Subtotal	*468.89*	*264.82*	*435.35*	*294.32*
Accommodation costs				
Accommodation staff[a]	483.06	717.68	394.01	551.39
Accommodation non-staff[a]	117.20	142.13	136.15	148.12
Domiciliary staff[b]	34.62	105.38	3.72	22.99
Respite care[b]	9.89	37.74	11.16	45.29
Subtotal	*644.91*	*815.77*	*528.80*	*652.16*
Total	***1113.80***	***803.43***	***964.15***	***565.35***

SD, standard deviation.

a For service users living in out-of-family staffed accommodation: intervention group $n = 36$, control group $n = 41$.

b For service users living independently, in adult family placements or in family homes: intervention group $n = 48$, control group $n = 44$.

TABLE 52 Costs per person per week (£) of health and social care resource use at the 10-month follow-up for the intervention ($n = 67$) and control ($n = 66$) groups

10-month follow-up: type of resource use	Intervention group ($n = 67$)		Control group ($n = 66$)	
	Mean cost (£)	SD	Mean cost (£)	SD
Non-accommodation costs				
Daytime activities	375.74	286.98	310.81	259.64
Psychotropic medication	2.07	9.72	1.67	8.40
Multidisciplinary meetings	10.84	33.37	4.52	21.88
Community-based services	20.38	45.82	15.66	17.59
Hospital-based services	10.82	37.14	3.72	9.89
Subtotal	*419.85*	*305.11*	*336.37*	*270.44*
Accommodation costs				
Accommodation staff[a]	399.57	535.80	394.70	586.45
Accommodation non-staff[a]	122.24	129.76	126.11	152.27
Domiciliary staff[b]	8.67	55.07	0.22	1.81
Respite care[b]	19.75	156.39	9.70	34.50
Subtotal	*550.23*	*655.82*	*530.72*	*700.73*
Total	***970.08***	***700.08***	***867.09***	***591.51***

SD, standard deviation.

a For service users living in out-of-family staffed accommodation: intervention group $n = 29$, control group $n = 29$.

b For service users living independently, in adult family placements or in family homes: intervention group $n = 38$, control group $n = 37$.

Table 53 shows comparative resource use costs between groups at the 10-month follow-up, controlling for differences at baseline. Mean adjusted differences show costs for the intervention group tending to be higher than for control subjects for non-accommodation costs, particularly in the case of daytime activities, and to be lower for accommodation costs, particularly the costs of staffing in out-of-family accommodation. Overall, the total adjusted mean cost was lower for the intervention group than for control subjects, but no differences were statistically significant. We are, therefore, unable to determine whether or not the excess cost of the intervention can be offset by future savings in health and social care resource usage.

TABLE 53 Comparative costs (£) of health and social care resource use at the 10-month follow-up, controlling for baseline levels (intervention, $n = 67$; control, $n = 62$)

Type of resource use	Adjusted mean difference[a]	95% CI		*p*-value
		Lower bound	Upper bound	SD
Non-accommodation costs				
Daytime activities	41.26	–59.36	141.88	0.422
Psychotropic medication	–0.05	–2.27	2.17	0.965
Multidisciplinary meetings	3.57	–5.39	12.54	0.434
Community-based services	0.77	–8.94	10.49	0.876
Hospital-based services	6.50	–0.79	13.79	0.081
Total non-accommodation costs	*50.56*	*–59.71*	*160.83*	*0.369*
Accommodation costs				
Accommodation staff	–44.35	–170.12	81.41	0.489
Accommodation non-staff	6.59	–22.44	35.62	0.656
Domiciliary staff	9.75	–28.91	48.40	0.621
Respite care	9.14	–4.90	23.18	0.202
Total accommodation costs	*–66.12*	*–223.71*	*91.48*	*0.411*
Total	***–22.46***	***–191.71***	***146.79***	***0.795***

SD, standard deviation.

[a] Cost for intervention participants minus cost for control subjects. Adjustment made for baseline means.

Chapter 8 The experiences of service users, therapists and managers

The results for each of the three groups of participants will be described in turn, followed by a synopsis of the themes which are shared between the groups.

Service users

Eleven service users (eight males and three females) were interviewed. Their ages ranged from 22 to 44 years and their WASI FSIQ estimates from 54 to 64 years. Six interviewees lived with their families, four lived in supported accommodation and one lived alone. These demographics are typical of the overall sample (see *Table 10*).

Four key themes that emerged from the transcribed interviews are presented here with verbatim quotes to illustrate the meaning of each theme.

Theme 1: What we did in the group

Most service users described the overall purpose of the group:

> *Talking about your feelings, talking about things that you can do to control your anger.*

> *The group tried to help me calm myself down. . .not to get angry.*

as well as specific group activities, such as relaxation exercises:

> *You use your . . . put your toes up in the air, do your breathing, your arm, then go off into a happy place then.*

> *Techniques, like, you could count to 10 (. . .) and take deep breaths, and, if you get angry – walk away (. . .) and . . . just relax. (. . .) Just do something else, take your mind off the situation and do something, do something else.*

and role play:

> *We had a line (. . .) somebody pushed in and then somebody shouted at them and told them to get back in the queue (. . .) which I thought was funny.*

> *I was on the computer (. . .) doing some work, and M. . . came up to me and was like, 'J . . ., I want to talk to you,' and I was like, 'Wait, I'm busy,' . . . I was acting.*

All service users' responses indicated that they had clear memories of the group sessions.

Theme 2: What it was like to take part

A number of service users reported to have been nervous before they started the group:

> *I was nervous (. . .) because it was a new thing for me.*

> *I just felt shy about it.*

but that this was short-lived and the overwhelming majority of accounts were positive evaluations:

> *. . . just find it interesting and fun.*
>
> *It was good. I enjoyed everything.*
>
> *I love that group.*

Although the interviewer repeatedly prompted each of the service users to suggest improvements for future groups or state what they had found least useful/positive, negative evaluations were reported by only two participants: one who commented on his dislike of another group member and another who found one part of the relaxation exercises difficult.

Most of the participants emphasised the therapeutic value of sharing experiences and the opportunity to talk about problems, as well as their recollections of having experienced a sense of fun and enjoyment:

> *We couldn't stop laughing.*
>
> *I liked people talking to me.*
>
> *I worked out that if you're swapping stories it helps each other out.*

Theme 3: What difference the group made to my life

The service users were able to identify a number of positive changes in their lives which they attributed to the CBT group intervention and spoke of using the newly acquired strategies in their everyday lives. Most focused on the use of 'walking away', 'counting to 10' and 'asking for help'. Several participants described incidents in which they had used strategies successfully:

> *That (relaxation exercises) is what kept me from going overboard today.*

They described improved relationships with peers:

> *Me and my housemate used to argue and I used to go off on one, but since this course I haven't done that.*

and improved mood and the ability to regulate their arousal state:

> *I'm just the same person, but . . . if I get angry I talk about what's annoying me . . . makes me feel much, what's the word, makes me feel much better . . . with myself.*
>
> *Cause I'm a different person now, I used to be all boisterous but I'm not no more, I've calmed right down.*
>
> *Not in a bad mood in the house now. (. . .) Eh . . . up in the morning. Not mad. Not mad. Not else. Stop the crying . . .*

One service user described how these improvements were limited to the settings in which he felt comfortable and were not apparent in a club he attended where he was not happy.

Theme 4: Presenting a positive self

Participants frequently expressed pride in what they had learned in the group and achieved in real life, such as the ability to control anger. They also mentioned the praise they had received from others:

Just go for a walk on your own and count to 10 in your head. (. . .) That's what I done good with that.

> *Happy that (therapist) told (key worker) that I worked hard.*

Quantitative outcomes

The uniformly positive feedback from the service users interviewed raises the question of whether they were typical of their group or had experienced particularly positive clinical outcomes. *Table 54* compares the interviewees with the other service users in the intervention group of the trial who were not interviewed. The interviewees had higher PI scores and slightly lower PACS scores at baseline, with larger changes in both their PI and their PACS scores at the 16-week follow-up assessment.

Therapists

Nine therapists (five males and four females) were selected purposively as those who had been most active in terms of running groups. Their ages ranged from 24 to 57 years and the length of time they had been employed in learning disability services from 9 months to 24 years. They included five support workers, two senior support workers and two managers. None had prior formal training in CBT, counselling or psychotherapy.

Seven key themes emerged from their accounts of the experiences of taking on the role of therapist and facilitating the anger management groups. These are summarised below and illustrated with verbatim quotes from the interviews.

Theme 1: Getting started; hopes, fears and readiness

Participants felt that taking on the role of therapist was an opportunity with a number of potential benefits, such as the chance to develop their professional knowledge and skills, enhance their support of service users, and enable their service organisation to develop current models of proactive support for service users with anger issues and related behavioural difficulties:

> *We thought it would be a good thing, one for our service users but secondly for ourselves, perhaps to get some ideas to use as a tool for our own working practices . . . I'd perhaps get some more insight into one or two of the clients and there might be a general thing that we could use in other ways with other clients.*

However, despite recognising their involvement as an opportunity, all participants described feeling initially apprehensive about running the anger groups. Reasons given related to personal doubts regarding how 'qualified' they were to run a CBT group and feeling daunted by taking on what they considered to be

TABLE 54 Comparison of clinical outcome for service users who were or were not interviewed

		Baseline		16-week follow-up	
Outcome	Interviewed?	*n*	Mean/median	*n*	Mean/median
Self-reported PI[a]	Yes	11	50.6 (18.3)	11	45.4 (22.4)
	No	80	42.0 (19.0)	66	40.9 (19.1)
Self-reported PACS[b]	Yes	11	22.9 (13.5 to 33.3)	11	37.5 (30.2 to 48.4)
	No	78	25.0 (14.6 to 37.5)	63	33.3 (26.0 to 43.8)

a Mean [standard deviation (SD)].
b Median (IQR).

a specialist role. Participants expressed their uncertainty about how effective and credible they would be as therapists:

> *The only fear I had was would they be able to listen to me, would they think wait a minute you're just a support worker, why should I listen to you?*

Other concerns related to more practical issues, such as whether or not they would be able to protect the time within their working week to run the group. Some felt concerned about how service users would respond, for example querying how well they would engage or form a cohesive group. Notwithstanding their initial feelings of doubt and apprehension, participants were unanimous that the training they received from the clinical psychologist provided sufficient information and guidance to feel prepared and confident to run the group and to understand the principles of group work and the CBT model. The assurance of regular supervision from a clinical psychologist throughout the intervention and provision of a manual as a guide was mentioned as helpful in allaying their fears.

Theme 2: Using the manualised approach

Generally, participants provided positive feedback about the manualised approach. They reported that the manual provided a useful framework and that the session plans outlined were practical and had saved them time in preparation. The manual was described as user-friendly and jargon free, and the fact that all the relevant resources and materials were provided was considered helpful:

> *The manual was absolutely first class because it told almost verbatim what you were going to be doing and that instilled you with confidence because you knew what was coming next. The other worker and I would meet before each group and say 'this is what we're doing, this is how we're going to approach it'.*

However, two of the participants commented that they had experienced the manualised approach as somewhat constraining and they would have liked more flexibility to modify the session content and how long to spend on different activities. A difficulty expressed in this respect was feeling under pressure to bring discussions that were in full flow to a halt to fit everything in and finish on time.

The overall feedback about manual content was positive regarding the activities and taught techniques. The material was felt to be accessible to service users and the 12-week period for running the groups was thought to be about right. However, limitations were also highlighted. One participant mentioned that the technique 'count to 10' was perceived as unhelpful by group members. Two participants commented that role play in their groups had limited success (this was a principal technique used to help group members to increase their awareness of triggers to anger and to practise coping strategies). Group members were reported as either reluctant to take part in role play or, when they did, struggling to make meaning of it:

> *They did enjoy the role plays and they took part themselves, but it just seemed to be lost once the role play was finished. We tried different things and different strategies, there were three of us and we mixed them up and shuffled the pack . . . but everyone sort of agreed that the role plays were definitely the weakest part.*

Moreover, complex coping strategies that involved cognitive concepts such as 'thinking differently' and using assertiveness were considered to be too complicated for some group members:

> *You know, the idea of looking at it from someone else's perspective, she [group member] had the words but she only had half the idea if you see what I mean and her capacity is quite high so I think others were struggling more than that.*

Theme 3: Making the group work

Participants described factors that were essential to the groups running successfully. Skills of facilitation were considered as fundamental to the role of therapist and included working well with a broad ability range in the group. Communicating effectively, pitching the information at the right level and working at the right pace to aid understanding and help maintain engagement were considered important. Having people with differing levels of ability working together in the same group was mentioned as a difficulty. Two participants commented that tensions could arise when more able group members were quick to understand topics, whereas others required repeated explanations. However, having more able group members who helped to explain things could be positive, as it promoted supportive and cohesive group dynamics.

Other aspects of managing group dynamics included recognising individual differences within the group, such as encouraging quieter group members to develop their confidence and 'find their voice', avoiding more talkative people from dominating, and being able to manage the flow of the group discussions:

> *Everybody gets a chance to speak and everybody gets a chance to listen . . . some people would go off on a slight tangent but we would guide them back and I think that's basically through eye contact, your general style, your proximity to them and your empathy, or redirecting questions if someone kinda wanders slightly you can redirect a question to bring them back to where they should have been.*

Creating a therapeutic environment through the development of supportive relationships and trust within the group, while setting appropriate boundaries, was described as paramount, for example by keeping confidentiality and adhering to group rules:

> *We had rules and we posted them up on the wall every week and we would always go back if someone was butting in . . . and at the very top is privacy and what's said in the room stays in the room and the privacy thing was a big issue. But I think because the group trusted each other and they were discussing things and things were getting said and brought up, under normal circumstances people would be running about telling everyone, but with the group it seemed to stay private and things were never discussed out in the open.*

Although being fully aware of their remit to deliver a manualised group intervention, the participants recognised a need for group members to raise things that were important to them and, in so doing, demonstrated a flexibility to respond to individual needs. Participants encouraged the group members to share 'ownership' of the group and to steer the direction of the discussions where appropriate.

A number of participants felt that it was important to avoid establishing themselves as group leaders but to convey a sense of 'all learning together'. They did this by sharing their own experiences of anger, and some even completed the homework activity (although they had not been asked to do this). They felt that this not only helped to reinforce key messages of the group work, such as 'normalising' anger as one of many basic human emotions, but also provided opportunities to 'model' coping with anger. Participants who adopted this approach felt that it served a crucial function in helping service users to feel more ready to discuss their own experiences, particularly those who were initially reluctant to admit to anger difficulties:

> *It took them a while initially and I think bringing in scenarios where we'd get really, really cross and did something that we weren't proud of and us being to say 'No, I felt ashamed of what I did' . . . and because we were able to bring humour into it as well, but not laughing at what we'd done but being able to say 'I felt really ashamed and I had to go and sit in my bedroom on my own' and that sort of thing, being able to say it's okay to feel ashamed and it's ok to feel cross, upset, or crying, and that was good.*

Certain aspects of group dynamics were more challenging to manage. These included handling the level of openness within the group and disclosure of information of a highly sensitive or distressing nature. Engaging with the service users at a level different from what was normally expected and having to manage the personal impact of hearing emotive issues were highlighted as important. Supervision was identified as a mechanism for obtaining support:

> *Some things came out like really private you know about family and things. At first it was uncomfortable and it was giving me cause for concern, but we then had supervision ourselves so we were able to talk about it and discuss it . . . From a therapist point of view it was difficult because some of the things you are hearing aren't pleasant. You know what goes on and think you can't do anything about it, you can do as much as you can but you can't stop it all can you?*

Theme 4: Observing progress

Many accounts were given of service users making considerable progress in terms of increased anger control and personal development in other areas:

> *Self-confidence, communication skills improved as well, it improved understanding of emotions, it improved a lot of things and I think it improved anger levels as well which I think it should have done!*

It was recognised that better anger control led to systemic benefits, such as a sense of improved relationships and a more relaxed social environment at the day centre overall:

> *I think it's a good tool, I think the majority of it has worked for those who attended and I think because of that things here are a lot better . . . if we get another group in for some that haven't done it we might help those people, which then again has that knock on effect of making life that little bit easier for the rest of us.*

However, a few group members were described as having difficulty applying the skills taught in the group:

> *I'd like to say it was totally rewarding but it was also very frustrating because we'd go through things in the group and it was clear that people had an understanding . . . the interesting thing and very frustrating thing was that they could apply that knowledge to other people but they didn't always apply it to themselves. They talk about something here about how not to do it and they go straight back home and do it!*

Theme 5: The ingredients of success; factors influencing group outcomes

Participants commented on aspects of the group process that they thought contributed to service user progress. The development of self-awareness and control was a central factor, including developing awareness of triggers, recognising feeling angry, and making connections between thoughts, feelings and behaviour:

> *The main outcomes would be recognising what anger is, recognising the physical effects, recognising triggers and understanding techniques for dealing with these emotions, physical feelings and triggers and applying them and thinking about it afterwards. I think reflection is a big part of it as well, I think the hassle logs, they did their part because they allowed people to reflect.*

Offering alternatives through psychoeducation was considered as a key contributor to progress, as it increased group members' awareness of different strategies and offered them positive suggestions about what they could do rather than stressing what they should not do:

> *I think it's the feeling that people could choose, make choices about what they did, whether they could ignore something. It was the strategies I think that it gave, things you could do because quite often we say 'Don't get angry', but that's not very helpful, but you know do go and listen to some*

> *nice music, do walk away, do think that person's got out of the wrong side of bed today . . . these were useful things to offer people'.*

Finally, although two of the groups reportedly struggled with the role play, for the most part it was considered to be a crucial learning tool whereby group members could observe angry situations acted out, which helped them to gain insight and practise coping techniques:

> *Creating examples that people can relate to I think was a big factor you know, you could sit there for two hours and read something and people are like 'Well I sort of understand what you are talking about but where are you going with this?' and when you introduce a role play exercise it keeps people focused, you could find that people drift off and get a bit detached from what is being delivered. But when you're delivering information and you role play it, you demonstrate it and it brings it all together and that was good to see that work.*

Theme 6: Taking on the 'therapist' role

Participants recognised a contrast and continuity with their usual role. They experienced a contrast in terms of working in a more focused and at times more intense way, but they also identified a crossover of skills between the two roles:

> *But then as a day service worker or a support worker you deal with emotions every day and you have to do some kind of counselling role, sometimes you don't realise it but you do quite a lot of counselling roles in there. I think if you've got a good relationship with who's in the group to start with then you're kinda sorted when it starts.*

Several of the participants asked 'Was I really a therapist?' and preferred to think of themselves as a group leader or facilitator:

> *I think facilitator, yeah facilitator is a better word because the service users are really taking you where you are going, although we know we're guiding, the book's very good at guiding you where, but what comes out of the service users' mouths is very interesting. I do think it's based on relationships and bonding and trust, and to go with the flow. I enjoyed going with the full flow of it and I really didn't think it was a difficult task to do at all.*

In whatever way they interpreted the role, participants described feeling effective and confident and felt that their confidence grew over time. Some said that taking on the role had enabled them to develop closer relationships with service users, characterised by greater trust and a stronger bond than existed before:

> *It's as if we have all been through something together and we all seem to have like a bond that was formed, not that you treat anyone different but it just feels different with that group . . . I think it's because we shared so we're more open and honest with each other, I think it's just made us closer like groups become.*

Participants considered that the therapist role had helped them to develop their knowledge and skills by gaining a better understanding of anger issues and developing a different understanding of group members' support needs. Use of supervision was also regarded as a useful further way to develop skills and confidence in the role. Participants' enjoyment and satisfaction in running the groups was clear. Without exception, their comments expressed a sense of truly valuing the experience and the opportunity it provided.

Theme 7: The future; taking the group work forward

A number of participants had plans to run another group, albeit that finding the time and additional staff cover to run the group were potential barriers to doing so. Having the skills to run a group 'in house', especially in the current financial climate, was recognised as beneficial:

> *We're also at times asked by statutory agencies if we know can anybody run an anger management course so we say yes we can do that, because there aren't many. I mean one of the organisations that we did use has lost their funding and so that has been a loss to us . . . it's a matter of not accessing things very easily.*

Participants recognised that service users who had attended the groups would continue to require support to maintain their progress and that staff would need to take a proactive role in this. It was also noted that sharing information with other staff could enable knowledge and skills to be disseminated and increase the staff team's awareness of anger support strategies, which potentially could help to maintain gains that were made in the CBT group.

Managers: pre-intervention interviews

Managers of all of the services in the intervention group were interviewed by telephone ($n = 8$; some managers managed more than one centre). There were four female and four male participants who managed local authority or independent services. Their experience of working in learning disability services ranged from 1 to 30 years, with the majority of participants having more than 7 years' experience.

Before any intervention commenced in the organisations, the managers were asked why their service had opted to join the research trial, the nature of the challenging behaviours experienced, and current service practices and approaches to managing such behaviours.

The themes identified by the TA are described below under each of the interview questions with quotes to illustrate the meaning of the theme.

What made your service decide to join the research trial?

Theme 1: Opportunity

All managers considered the opportunity to take part in the trial to be beneficial to the service as a whole, not only for the service users but also for the staff. The staff training provided by the project was particularly appreciated. Some mentioned that this type of opportunity was a rarity:

> *I just felt it was a golden opportunity for our service users.*

Theme 2: To compare ourselves

One participant also noted that this was an opportunity to compare the service with other local services.

Theme 3: Like the approach

A number of participants spoke about the input their service received from other professionals and reported that their staff already had some basic knowledge of psychological approaches that were used within the service:

> *We have a lot of input from psychology so we're very interested basically.*

Theme 4: For the outcome

Most participants had an expectation that the intervention would result in a positive outcome for the service and stated this as the primary reason for participating in the trial:

> *. . . to enhance the service we can deliver.*

> *I am hopeful that we might actually see a reduction in incidents, that would be great.*

What are the current service policies and practices?

Theme 1: Training

All of the participants reported that some staff training on challenging behaviour was available in their service. However, most managers also reported that the training was inadequate and pitched at a basic level, with a focus on physical intervention to manage behaviours that challenge services, rather than more psychological approaches. This theme was discussed in greater depth when participants were asked to describe 'what doesn't currently work well?'.

Theme 2: Multidisciplinary working

All of the participants reported that current practice relied heavily on taking a multidisciplinary approach and developing good collaborative relationships with the local multidisciplinary team. This practice is discussed in greater detail in response to the question 'what works well?'.

Theme 3: Ideology

Finally, a number of the participants identified their service ideology as integral to service practice, indicating that ideology informs staff behaviour:

> *Staff remaining calm, the tone of their voice . . . picking up on non-verbal cues . . . is big within our philosophy.*

What are the causes of the behaviours that challenge your services?

Theme 1: Lack of consistent approaches

The majority of participants discussed how inconsistent staff approaches with service users contributed to the occurrence of challenging behaviour within the service.

Theme 2: Alcohol

The consumption of alcohol by service users was also identified by some as the cause of behaviours which challenge services:

> *. . . usually fuelled by alcohol.*

Theme 3: Past experiences

Participants also spoke about service users' damaging past experiences and a lack of continuity for them during transition from child to adult services. They identified these experiences as contributing factors to current problems:

> *He has been brought up in institutions and services and he very much resents that – he has got more anger in him.*

> *The information we received from children services was very, very poor.*

What are the consequences of behaviour that challenge services?

Theme 1: Exclusion

Participants acknowledged that if behaviour becomes too challenging for services then exclusion from the service can be the consequence for service users:

> *We had to go back to the local authority and say, in this instance, we believe he's actually placed at the wrong service.*

Theme 2: Fear and physical harm

All of the participants mentioned that challenging behaviour can result in fear, as well as actual physical harm, experienced by staff and services users:

> *It actually got to a point where, um, my own members of staff were sustaining injuries.*

> *The team have been kicked, punched, spat on . . .*

Theme 3: Staff sickness

Participants also identified potential long-term implications of behaviour that challenges services on the staff and the wider service as a whole, whereby the psychological and physical consequences of being on the receiving end of aggressive behaviour result in stress symptoms which in turn result in staff going on sick leave:

> *Staff members go off on long-term sickness with stress-related issues from an experience they've had.*

What works well?

Theme 1: Multidisciplinary teamworking

Every manager discussed the benefits of a multidisciplinary approach and appeared satisfied with the level and speed with which the local social and health professionals responded to requests for help.

> *We have liaised with health over the last couple of years around new training packages.*

> *The MDT team are very good, we've got a good speech and language team.*

> *We have a sessional consultant psychologist . . . we've also got a consultant psychiatrist . . . it's very much multi-disciplinary.*

> *If we are really struggling, we can call them any time.*

Theme 2: The beauty of forms

Some managers emphasised the importance of record-keeping and collecting information to throw light on the nature and causes of challenging behaviours in order to develop preventative strategies.

> *More emphasis on sort of record keeping and everything else, but I think the beauty of those sort of forms and everything else is looking at it, as it happens . . .*

Theme 3: Staff selection

A number of managers emphasised that staff have a vital role to play in supporting service users with challenging behaviour and that recruiting the 'right' type of person and developing a cohesive staff team are essential:

> *A good staff team knows the service users well.*

What does not work well?

Theme 1: Lack of training

All of the participants identified the lack of appropriate training as the main shortcoming in their service:

> *It would be far easier if we had staff trained in the field.*

> *We only do basic er, avoidance of behaviour training . . . it's fairly useless.*

> *Staff are not going to get involved . . . they have not been trained how to physically handle someone.*

Theme 2: Inconsistent staff approaches

Linked to the 'lack of training' theme the managers again mentioned inconsistency in approach on the part of their staff team as a major problem, which had a negative effect on the quality of the service.

Managers: post-intervention interviews

Once all the phases of the intervention had been completed (i.e. the service had received training, the groups had been run, and the 6-month follow-up data had been collected) follow-up telephone calls were made to the same participants to explore whether or not there had been any changes in their service following the intervention phase.

What is the service like now?

Theme 1: A positive experience

The participants unanimously used the term 'positive' in response to this question and described how the group intervention had been experienced in a positive manner by all concerned:

> *It has been a positive experience for the staff, the service users, the service in general and it seems to be run very well and the service users were happy and looking forward to each session, getting involved . . .*

Theme 2: Positive outcomes for service users

All of the participants expressed that there had been a noticeable difference in the majority of the service users who had participated in the group intervention:

> *I mean the service users have undergone some really noticeable changes.*

Positive outcomes included service users appearing calmer and more comfortable with discussing their feelings, not only in the group setting but also with the therapists outside of the group, and changes in how some of the service users coped with anger, such as speaking to staff about their feelings, anticipating that how they were feeling may result in challenging behaviour, and seeking support:

> *They're realising themselves when they are getting angry . . . they will even say it to the staff member.*

Moreover, they felt that the strategies learned in the group were applied by service users in 'real life':

> *You could actually see evidence of them (service users) trying to put in place what they've learned and experienced in the group.*

Theme 3: Positive changes in staff

All the managers also mentioned positive changes in the staff who had delivered the intervention. They noted an apparent increase in confidence in staff, which translated into their work with both service users and other members of the staff team.

Considering the lack of consistency in the way in which staff approached people with challenging behaviour previously identified as a potential cause of challenging behaviour, it is important to note that most managers observed an improvement post intervention:

> *I suppose the best thing is all of the staff having the same approach.*

They also reported that staff had become more able to reflect on their working practices and how they might impact on the service users' experiences and behaviour:

> *It's sort of given them a bit of an insight into you know, different ways of working.*

Any plans for further group work?

The participants were asked whether or not they intended to offer group work in the future. All of the managers reported that they were planning future groups.

Theme 1: Refresher groups

The majority of the participants reported that they would use a similar group format to the one used in the intervention but some future groups were planned as refresher sessions rather than the whole programme offered to new service users:

> *There may be a need and an opportunity to revisit the lessons learnt.*

Theme 2: Lay therapist selection

Some participants also acknowledged that, had they anticipated the full extent of the perceived positive impact of the intervention, they might have given a greater consideration to the lay therapists identified to deliver the group:

> *. . . with hindsight it may be better to have picked some other staff that may be had more to learn from it.*

> *. . . I want staff to run it who want to do it . . .*

Theme 3: Generalisation into the broader service environment

Participants also discussed the potential positive impact on the service if the strategies discussed in the groups could be introduced systematically into the wider service environment:

> *. . . the staff that were involved in the groups . . . they've obviously spoken to their colleagues and the colleagues have picked up on things . . .*

Any suggestions for improvements?

Finally, managers were asked to think of suggestions for improving the group intervention.

Theme 1: Increase accessibility and inclusivity

One manager suggested that the group intervention should be made accessible to service users with more severe intellectual disabilities:

> *If there was another version created, more set up for those with minimal or lesser communication skills.*

Another suggested that the manual could be improved by using more inclusive materials:

> *. . . teaching materials . . . didn't always take account of different genders and ethnicities.*

Theme 2: Shorter programme

One manager stated that it would be an improvement if the intervention was shortened:

> *. . . to have fewer sessions basically.*

Shared themes between the three groups of participants

The analyses of the three sets of interview data have thrown up a number of shared or interlinking themes, which are described below.

Theme 1: Benefits of group work

Both service users and therapists experienced the group as an environment where it had been possible to get to know each other better and in a different way, developing relationships and trust by sharing experiences and having fun.

All three groups (service users, therapists and managers) commented on the benefits of the group 'spilling out' into the wider service, changing the organisational culture for the better and, in some cases, having a 'knock-on' effect where the ability to control anger on the part of some of the service users reduced the number of incidents and, therefore, improved relationships, the environmental groups, and the emotional well-being of others attending and working in the service.

All three participant groups also noted that a number of service users' self-awareness and self-control had noticeably improved as a result of group attendance.

Managers and therapists observed that staff came to work better with each other and in a more consistent manner with service users. They also saw the group intervention and the staff training involved as a springboard to further opportunities for service development, and appeared motivated to run more groups in the future, albeit in some cases refresher sessions rather than providing the whole course to a new set of service users.

Theme 2: Using 'in-house' therapists

Managers, service users and therapists all noted the significant advantages of having 'in-house' therapists who are present and available to help with 'homework' and encourage the use of skills learned in the group in other contexts, thereby enabling generalisation and maintenance of skills over time.

Therapists emphasised the positive impact of facilitating the group (and receiving training and clinical supervision from psychologists) on their confidence and job satisfaction, despite initial anxieties about taking on the role. They also reported that the experiences gained during the training and intervention phases of the project had increased their insight into service users' problems, which allowed them to respond in more psychologically informed and skilled ways. These positive impacts were echoed by their managers.

Theme 3: Using the manual

Most of the participants in all three groups regarded the manual as a useful tool, providing structure and thus reassurance to the therapists. The specific exercises contained in the manual were considered to have been effective and enjoyable. Role play was remembered more clearly and fondly by service users and (with two exceptions) therapists than any of the other exercises, indicating that these 'in vivo' experiences not only provided insight into specific behavioural and cognitive response modes and their functionality, but also promoted memory retention.

Service users did not suggest changes to the manual (despite being prompted and encouraged in a number of ways to critique the course and the materials used). However, managers and therapists proposed a number of changes which mostly concerned lack of flexibility, accessibility and inclusivity of the manual, and reducing the number of sessions needed to complete the course.

Participants' response to feedback on the trial outcomes: data credibility check

Separate events were held to deliver the findings to service users, family carers and lay therapists who had run the groups. In their feedback, service users and lay therapists provided a strong endorsement of the findings that were presented. In particular, they emphasised the strong bonds that developed in the course of the groups. Service users felt that they had made friends with other group members and learned how to respect and work with each other. They also agreed with the particular benefit of learning to express their emotions more appropriately. In addition to feelings of anger, they had also talked about the benefits of learning to express and manage other distressing feelings. The lay therapists expressed similar views, and agreed that group members had bonded with one another and sometimes become friends. They felt this was particularly helpful for the group members because their problems with anger often meant that they had difficulty forming and maintaining relationships. Moreover, the lay therapists also agreed that they had developed better relationships with the group members, and several individuals described how group members would seek them out for help and support after the group had finished, in preference to other staff members.

Service users and lay therapists attending the feedback sessions confirmed that a number of the activities, and in particular the role plays, were particularly memorable and effective components of the intervention. They reported that taking part in these activities together had helped to foster closer relationships between the lay therapists and service users. Service users seemed to have particularly enjoyed watching the lay therapists role playing situations in which they became angry. When talking about the findings concerning the outcomes of the therapy, service users talked about how the group had helped them to gain more self-control. However, it was also interesting that when asked what changes they would make to groups run in the future, service users said that the groups should be run for longer, as if they were uncertain that the improvements would last unless they received ongoing support.

Family carers also expressed concern that improvements would not be maintained unless the groups continued. However, it also became apparent that there were family carers who did not feel the group was of particular relevance to them, as their relative's difficulties arose in the day centres, where they socialised with other people. In contrast, other family members took a keen interest in the group, as their relative's anger problems were also manifest at home. For example, one family member, whose sister had presented considerable challenges in the family home, felt that her sibling's ability to express her feelings more appropriately had led to a significant change in her behaviour. Her self-harm and aggression towards others reduced, which her sister thought had been born out of frustration at being unable to express her feelings. It was also noteworthy that the family carers who came to the feedback session were keen to hear about the research findings, because they believed they had few sources of professional support and thought that the specialist health and social care system was geared to crisis management. They felt that help would be given only if they reached a stage when they could no longer cope. In their view the groups offered a more proactive and effective approach to dealing with their relative's difficulties.

Chapter 9 Factors influencing clinical outcomes: a pre–post study of the anger management intervention

Introduction

A pre–post study was undertaken to further assess the manualised anger management intervention after the cluster randomised trial. This took advantage of the fact that, for ethical reasons, the intervention was delivered to the groups in the control arm following the 10-month follow-up of the trial, hence increasing the sample size. This analysis explored features at the service user, lay therapist and centre level that may be associated with better or worse outcome, with a specific focus on understanding what works, for whom and in what setting. This reflects aspects of realistic evaluation and is focused on implementation following on from the randomised trial.[147] Four factors were identified from the literature, two of which related to the service user (intellectual ability and mental health) and two to their experience of the intervention (compliance with the intervention and fidelity of delivery).

1. Intellectual ability

There is some evidence that intellectual ability influences the outcome of anger management interventions for people with intellectual disabilities but the data are variable. Three studies have reported that outcomes were better in more intellectually able participants, but inconsistently:[12] one study[41] found a relationship with receptive language ability as assessed by the BPVS, a second[39] found a relationship with Full-Scale or Verbal IQ but not Performance IQ, whereas a third[42] found a relationship with non-verbal ability but not receptive language ability. A fourth study found no significant relationship between intellectual ability and outcome.[49] Nevertheless, on the balance of this evidence, we predicted that higher levels of intellectual ability (IQ and/or BPVS scores) would be associated with better outcomes for anger management.

2. Mental health

It is well established that depression (but not anxiety) is one of the strongest risk factors for non-compliance with medical treatment.[148] Depression has also been reported to predict a poor outcome for treatment of externalising psychological disorders, such as substance abuse[149] or bulimia.[150] Consistent with this literature, high levels of depression and low self-esteem (but not anxiety) were associated with a poorer outcome for anger management.[151] We therefore predicted that high levels of depression and/or low self-esteem would be associated with poorer outcomes in the present study.

3. Compliance

There is a well-established dose–response relationship in psychotherapy, with the greatest gains occurring in early sessions and diminishing returns thereafter.[152,153] A recent meta-analysis of anger studies in the general population confirmed that effect sizes increased significantly with more sessions, although the differences were relatively small: the effect size for 12 sessions was roughly 10% larger than that seen with four sessions.[64] The mean number of anger treatment sessions delivered was 8.5. It was suggested that eight sessions should be adequate to demonstrate decreases in anger, and that treating angry clients beyond eight sessions provides limited further benefit.[64] However, psychological interventions for people with intellectual disabilities typically progress more slowly than with more intellectually able clients.[154] On the basis of this literature, we predicted that outcomes would improve with the number of sessions attended.

4. Fidelity

There is evidence that the fidelity of delivery of CBT makes an important contribution to the effectiveness of the intervention.[62,63] The above-mentioned meta-analysis of 96 studies of anger treatment in the general population reported that manualised interventions achieved better outcomes than non-manualised interventions (effect size: 0.81 vs 0.76) and studies that used fidelity checks achieved better outcomes than those that did not (effect size: 0.85 vs 0.73), albeit that neither effect achieved statistical significance ($p = 0.059$ and 0.090, respectively).[64] We predicted that higher fidelity would be associated with better outcomes.

Results

A series of multilevel regression analyses were undertaken using data from all participants in the 24 centres for which 16-week post-intervention follow-up data were available (*Figure 12*): 13 from the first phase of data collection and 11 from the second phase (total $n = 91–103$). Home carer data were not included in the pre–post analysis because the number of participants providing these data was substantially smaller than the number of key worker and service user reports. Those who were followed up were similar to those who were lost to follow-up in terms of pre-intervention clinical outcomes. However, there were some differences by region [60% of participants in England did not complete post-intervention assessments compared with 30% of participants in Scotland and 11% in Wales ($p < 0.001$)], centre type [30% of participants in local authority centres completed post-intervention assessments compared with 70% in non-local authority centres ($p < 0.001$)] and the number of sessions [median (IQR) attended was 11 (9 to 12) for participants who completed post-intervention assessments and 0 (0 to 0) for those who did not ($p < 0.001$)]. These differences largely reflect centre-level, rather than participant-level, dropout.

The dependent variable was the post-intervention level of the outcome variable. The pre-intervention level of the dependent variable was controlled by entering these values in the first block of the regression model along with service user demographics. (This was the baseline value for participants in the intervention groups and the 10-month follow-up value for participants in the control groups.) Other potential predictor variables were then entered in subsequent blocks representing:

- service user demographics (including intellectual disability)
- baseline measures of service user mental health
- lay therapist characteristics
- centre characteristics
- implementation quality (compliance and fidelity).

The variables entered were listed in *Table 6*.

The main outcome variables considered were the service user and key worker PI and PACS reports, with further exploratory analyses of the PACS-IPT and challenging behaviour (ABC). Mean pre- and post-intervention values of the outcome variables [with standard deviations (SDs) and 95% CIs] are shown in *Table 55*. The results are shown separately for the two waves of participants (the original intervention group and the erstwhile control subjects). Adding trial arm (wave) as an explanatory variable into each of the regression models did not significantly change any of the outcomes, and the variable itself was never statistically significant.

Partial correlations between the outcome variables controlling for their pre-intervention levels are shown in *Table 56*. As was seen in the baseline assessment (*Table 21*), there were significant correlations between service user and key worker ratings for both the PI and the PACS, and between service user PI and PACS scores.

For all outcome variables, pre-intervention values were a significant predictor of post-intervention values ($p < 0.01$). *Table 57* shows partial correlations between the four main outcome variables and the six predictor variables for which a priori predictions were made, controlling for pre-intervention levels of the outcome variable.

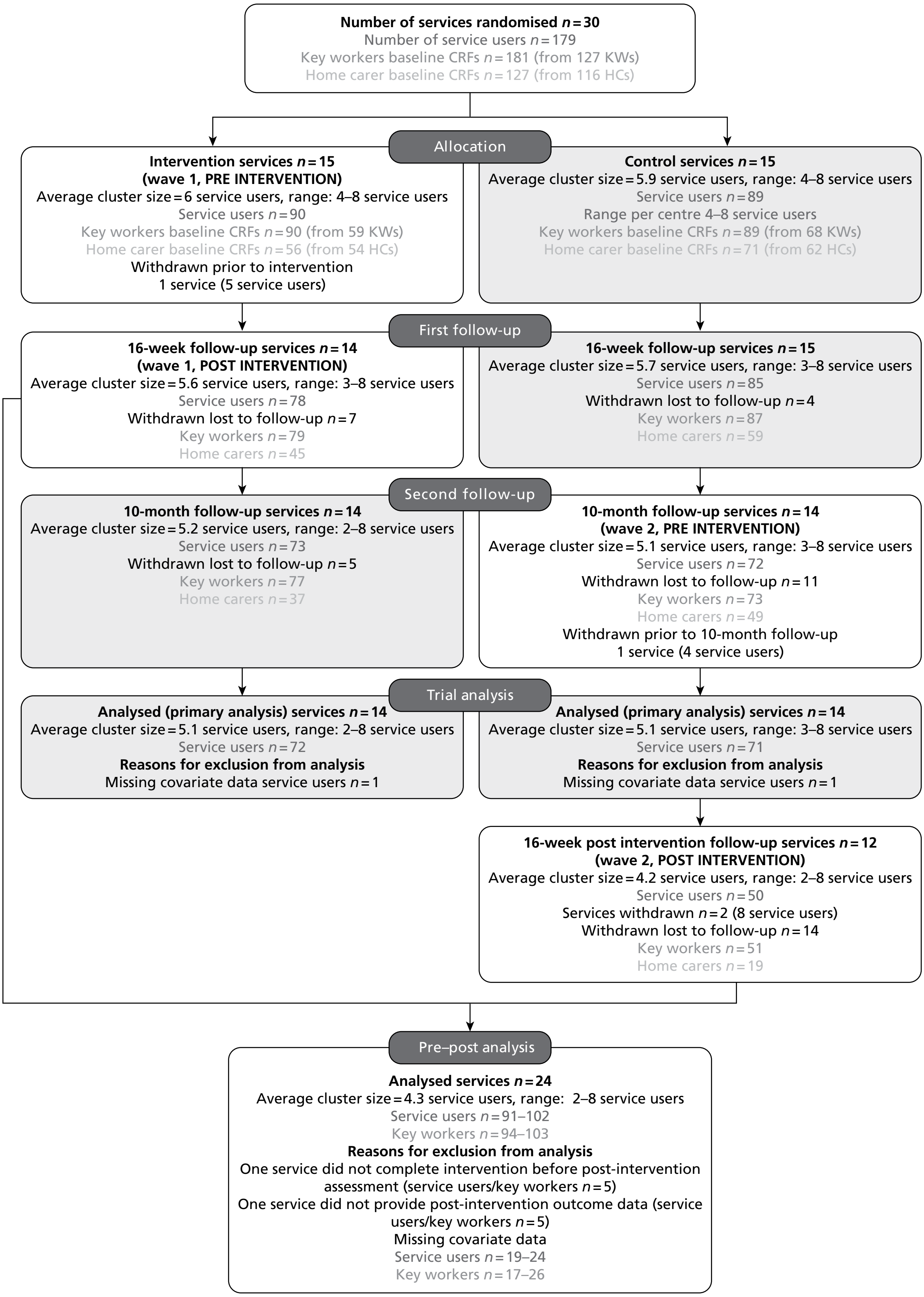


FIGURE 12 STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) participant flow diagram. CRF, case report form; HC, home carer; KW, key worker.

TABLE 55 Pre- and post-treatment values of clinical outcome measures[a]

<table>
<tr><th rowspan="2">Respondent</th><th rowspan="2">Measure</th><th rowspan="2">Complete cases</th><th colspan="3">Pre treatment</th><th colspan="3">Post treatment</th></tr>
<tr><th>Mean (SD)</th><th colspan="2">95% CI</th><th>Mean (SD)</th><th colspan="2">95% CI</th></tr>
<tr><td colspan="9"><i>Wave 1</i></td></tr>
<tr><td>Service user</td><td>PI</td><td>58</td><td>41.9 (18.9)</td><td colspan="2">36.9 to 46.8</td><td>43.3 (18.9)</td><td colspan="2">38.3 to 48.3</td></tr>
<tr><td></td><td>PACS</td><td>56</td><td>25.4 (15.8)</td><td colspan="2">21.2 to 29.6</td><td>41.0 (18.6)</td><td colspan="2">36.0 to 46.0</td></tr>
<tr><td>Key worker</td><td>PI</td><td>59</td><td>30.8 (11.6)</td><td colspan="2">27.8 to 33.9</td><td>31.5 (13.8)</td><td colspan="2">27.9 to 35.1</td></tr>
<tr><td></td><td>PACS</td><td>56</td><td>13.9 (11.6)</td><td colspan="2">10.8 to 17.0</td><td>25.0 (12.7)</td><td colspan="2">21.6 to 28.4</td></tr>
<tr><td></td><td>ABC</td><td>57</td><td>19.8 (14.2)</td><td colspan="2">16.1 to 23.6</td><td>16.4 (14.5)</td><td colspan="2">12.6 to 20.3</td></tr>
<tr><td></td><td></td><td></td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td></tr>
<tr><td>Service user</td><td>PACS-IPT</td><td>57</td><td>3.5</td><td>19.3</td><td>77.2</td><td>8.8</td><td>29.8</td><td>61.4</td></tr>
<tr><td colspan="9"><i>Wave 2</i></td></tr>
<tr><td>Service user</td><td>PI</td><td>44</td><td>46.4 (18.2)</td><td colspan="2">40.8 to 51.9</td><td>44.5 (19.7)</td><td colspan="2">38.5 to 50.5</td></tr>
<tr><td></td><td>PACS</td><td>35</td><td>28.8 (19.0)</td><td colspan="2">22.2 to 35.3</td><td>30.1 (20.7)</td><td colspan="2">23.0 to 37.2</td></tr>
<tr><td>Key worker</td><td>PI</td><td>44</td><td>34.7 (14.9)</td><td colspan="2">30.1 to 39.2</td><td>28.8 (13.1)</td><td colspan="2">24.8 to 32.8</td></tr>
<tr><td></td><td>PACS</td><td>38</td><td>14.4 (9.2)</td><td colspan="2">11.4 to 17.4</td><td>19.0 (14.1)</td><td colspan="2">14.4 to 23.7</td></tr>
<tr><td></td><td>ABC</td><td>42</td><td>15.2 (10.7)</td><td colspan="2">11.8 to 18.5</td><td>11.6 (9.6)</td><td colspan="2">8.6 to 14.6</td></tr>
<tr><td></td><td></td><td></td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td></tr>
<tr><td>Service user</td><td>PACS-IPT</td><td>37</td><td>5.4</td><td>37.8</td><td>56.8</td><td>24.3</td><td>32.4</td><td>43.2</td></tr>
<tr><td colspan="9"><i>Total</i></td></tr>
<tr><td>Service user</td><td>PI</td><td>102</td><td>43.8 (18.6)</td><td colspan="2">40.2 to 47.5</td><td>43.8 (19.2)</td><td colspan="2">40.1 to 47.6</td></tr>
<tr><td></td><td>PACS</td><td>91</td><td>26.7 (17.1)</td><td colspan="2">23.1 to 30.2</td><td>36.8 (20.0)</td><td colspan="2">32.7 to 41.0</td></tr>
<tr><td>Key worker</td><td>PI</td><td>103</td><td>32.5 (13.2)</td><td colspan="2">29.9 to 35.1</td><td>30.4 (13.5)</td><td colspan="2">27.7 to 33.0</td></tr>
<tr><td></td><td>PACS</td><td>94</td><td>14.1 (10.6)</td><td colspan="2">11.9 to 16.3</td><td>22.6 (13.5)</td><td colspan="2">19.8 to 25.4</td></tr>
<tr><td></td><td>ABC</td><td>99</td><td>17.9 (13.0)</td><td colspan="2">15.3 to 20.4</td><td>14.4 (12.8)</td><td colspan="2">11.8 to 16.9</td></tr>
<tr><td></td><td></td><td></td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td><td>Not (%)</td><td>A little (%)</td><td>Very (%)</td></tr>
<tr><td>Service user</td><td>PACS-IPT</td><td>94</td><td>4.3</td><td>26.6</td><td>69.1</td><td>14.9</td><td>30.9</td><td>54.3</td></tr>
</table>

[a] Values for PI, PACS and ABC are mean (SD) with 95% CI. For the PACS-IPT the table shows the proportion of service users rating themselves as not angry, a little angry or very angry in the situations described. Wave 1 refers to the initial group of participants who received the intervention (the intervention group from the main trial) and Wave 2 refers to the second group of participants who received the intervention (the control group from the main trial).

TABLE 56 Correlations between the main outcome variables[a]

	Service user PI		Key worker PI		Service user PACS	
	r	*p*-value	r	*p*-value	r	*p*-value
Key worker PI	**0.255**	**0.006**				
Service user PACS	**0.202**	**0.037**	0.086	0.382		
Key worker PACS	0.053	0.589	0.011	0.908	**0.200**	**0.048**

a The values in the table are partial correlations, controlling for the pre-treatment values of both variables, with significant correlations shown in bold text.

TABLE 57 Correlations between predictor and outcome variables[a]

	Service user				Key worker			
	PI (99)		PACS (88)		PI (100)		PACS (91)	
Measure (*n*)	r	*p*-value	r	*p*-value	r	*p*-value	R	*p*-value
IQ	–0.002	0.981	0.004	0.967	–0.119	0.198	0.043	0.653
BPVS	0.074	0.438	0.089	0.367	–0.038	0.685	0.066	0.498
GDS	–0.077	0.407	0.104	0.285	0.175	0.054	0.017	0.861
RSES	–0.072	0.440	–0.121	0.211	**–0.241**	**0.008**	0.002	0.982
NSessions	–0.106	0.291	0.058	0.585	0.029	0.776	0.131	0.201
Fidelity	**0.426**	**0.001**	**0.259**	**0.014**	**0.279**	**0.005**	0.029	0.780

NSessions, number of sessions attended.

a The table shows partial correlations, controlling for the pre-treatment levels of the outcome variable, with significant correlations shown in bold text.

Prediction of outcomes

Table 58 summarises the significant and near-significant predictors identified in the final regression models for the service user and key worker PI and service user PACS, after controlling for their pre-intervention levels. The regression analysis did not identify any significant predictors of key worker PACS scores.

Full details of the final regression models are shown in *Appendix 5*. The analyses did not identify any significant effects of centre characteristics, but significant effects were identified within each of the other four blocks of variables (see *Table 58*).

Service user demographics

The only significant demographic effect was an association between higher IQ and larger decreases in key worker PI ratings. There was no significant effect of receptive language ability. The service users' age and gender were not significant predictors of any of the outcome measures.

Service user pre-intervention mental health

Higher pre-intervention levels of depression and lower self-esteem were associated with smaller decreases in key worker-rated PI scores.

Higher baseline anxiety levels predicted less improvement in coping skills (service user PACS). This effect is in the opposite direction to that described in the main trial but as both of these results were of marginal

TABLE 58 Variables predictive of clinical outcomes in regression analyses

	SU PI		KW PI		SU PACS	
Variables	β	*p*-value	β	*p*-value	β	*p*-value
Block 1: Service user demographics						
Age	–0.258	0.061	–0.174	0.086		
Gender (males vs females)	–5.10	0.080				
FSIQ			**–0.334**	**0.040**		
Receptive language ability						
Block 2: Service user baseline mental health						
Depression			**0.764**	**0.004**	0.838	0.077
Self-esteem			**–0.771**	**0.034**		
Anxiety			–0.244	0.082	**–0.495**	**0.045**
Quality of life						
Control over challenging behaviour						
Block 3: Lay therapist characteristics						
Age	**0.795**	**0.006**				
Gender (males vs females)					**13.26**	**0.044**
Years working in intellectual disability services						
Highest qualification						
Block 4: Centre characteristics						
Type of centre						
Region						
No. of participants in the group						
Block 5: Implementation quality						
No. of sessions attended	**–1.21**	**0.012**				
Fidelity of delivery	**0.504**	**0.016**				

KW, key worker; SU, service user.

The table shows unstandardised estimates, with p-values, of significant (bold text) and near significant ($0.05 < p < 0.1$) predictors. 'β' is the regression coefficient and refers to the change in outcome per one unit change in covariate.

significance ($p = 0.048$ and $p = 0.039$, respectively), and considering the large number of analyses that have been conducted, they may represent chance findings.

Some non-significant trends in relation to depression and anxiety scores were also noted (see *Table 58*). No significant effects were associated with baseline measures of quality of life (ComQoL) or key workers' attributions of the service users' control over challenging behaviour (CBS).

Lay therapist characteristics

There was no effect of experience or educational qualifications but better outcomes were achieved by younger lay therapists (larger decreases in service user PI scores) and by female lay therapists (larger increases in service user PACS scores).

Implementation quality

The number of sessions attended and fidelity of delivery were associated with reduced and increased service user PI scores, respectively.

Tests of a priori predictions

Intellectual ability

There was some support for the hypothesis that IQ would predict outcome: post-intervention key worker PI scores were lower relative to pre-intervention levels in those of higher intellectual ability (see *Table 58*). However, IQ was not significantly associated with service user PI scores or with either set of PACS scores.

Mental health

There was also some support for the hypothesis that the intervention would be less effective in participants with higher pre-intervention levels of depression or lower self-esteem. These two variables were significant and independent predictors of a smaller post-intervention decrease in key worker PI scores (see *Table 58*). Again, there was no effect on service user PI scores or on either set of PACS scores.

As the WASI is very insensitive towards the bottom of the scale ($IQ = 50$), a further analysis was undertaken using a different measure of intellectual ability. In the baseline analysis, service users' ability to use rating scales was evaluated as part of the ComQoL assessment. Some service users were able to use both three- and five-point rating scales, whereas others were able to use only a three-point scale. (Those who were unable to use even a three-point scale were excluded from the trial.) The performance of the more able ($n = 36$) and less able ($n = 90$) groups was compared on the four main outcome variables, service user and key worker post-intervention PI and PAC scores, using ANCOVA (controlling for baseline scores). All four comparisons were non-significant ($p \geq 0.217$).

Compliance

There was some support for the hypothesis that outcomes would be better among participants who were more compliant with the intervention. The number of sessions attended was not significantly correlated with any of the outcomes (see *Table 57*). However, when included with other variables in the regression analysis, compliance emerged as a significant predictor of service user PI, with reduced post-intervention PI scores in those who attended more sessions (see *Table 58*). Attendance was not associated with the other outcomes.

An interaction term was added to the model to examine whether or not the effect of attendance on service user PI varied as a function of the pre-intervention service user PI score. This interaction was non-significant ($p = 0.52$).

Fidelity

There was a significant correlation between fidelity and increased service user and key worker PI scores and service user PACS scores (*Table 57*). However, only the association between fidelity and service user PI scores was significant in the regression analyses. The direction of effect was opposite to that predicted, with higher fidelity associated with higher PI. This effect is explored further below (see *Further analysis of the effect of fidelity to increase self-rated Provocation Index scores*).

Interaction terms were fitted to the model to examine whether this effect varied as a function of region, baseline PI score or number of sessions. All interactions were non-significant ($p \geq 0.649$), indicating that the association of fidelity with PI did not differ between regions, and was not greater in participants with low baseline PI scores or with greater exposure to the intervention.

Exploratory analyses

The PI and PACS results were explored further by fitting interaction terms to the regression models. As there were regional differences in pre-treatment PI and PACS scores, the analysis was repeated for all four variables (service user and key worker PI and PACS), including a pre-treatment score by region interaction term. All four interactions were non-significant ($p \geq 0.50$). Interaction terms were also added to the key worker PI model to examine whether or not the effects of any of the variables that predicted post-intervention PI (IQ, depression and self-esteem) varied as a function of pre-intervention key worker PI score. All three interactions were non-significant ($p \geq 0.097$).

An exploratory analysis examined predictors of the decrease in challenging behaviour (see *Table 55*). The ABC-H and ABC-I were combined for this analysis, as these scores were highly correlated (see *Table 22*) and had responded similarly to the intervention (see *Table 47*). There was a significant correlation (controlling for pre-intervention scores) between post-intervention key worker PACS and ABC scores ($r = 0.255$, $p < 0.005$) but the regression analysis did not identify any significant predictors of ABC scores. The final regression model is included in *Appendix 5*.

A final exploratory analysis was undertaken of the decrease in PACS-IPT scores (see *Table 55*). The data for this analysis were the median PACS-IPT scores, which were analysed using a ranked ANCOVA (see *Chapter 2*). The final model (see *Appendix* 5) included only two significant predictors. One was a regional difference, with greater reductions in anger in Scotland and to a lesser extent England than in Wales. The other was a larger effect in lay therapists with intermediate educational qualifications relative to those with the highest qualifications ($p = 0.017$); however, as the analysis included only the lead lay therapist in each group (i.e. total $n = 24$) the numbers at each of the four educational levels were small, so this finding must be treated with caution. Notably, fidelity did not appear in the final PACS-IPT model, unlike that for the self-rated PI.

Further analysis of the effect of fidelity to increase self-rated Provocation Index scores

In order to understand better the result that higher fidelity of delivery was associated with an increase in self-rated PI scores, three further exploratory analyses were undertaken.

Does the effect of fidelity on Provocation Index scores follow from an effect on Profile of Anger Coping Skills scores?

One possibility is that higher PI scores might be associated with a greater awareness of anger issues. Lay therapists who deliver the intervention with greater fidelity might increase service users' awareness of anger issues, with a consequent increase in self-rated PI scores, as a by-product of greater success in teaching the use of anger coping strategies. In other words, we hypothesised that increased self-ratings on the PACS might serve as a mediator between fidelity and self-ratings on the PI.

Possible mediation was analysed using the SPSS (SPSS Inc., Chicago, IL, USA) macro for multiple mediation.[155] The analysis calculates the direct effect of fidelity on post-intervention self-reported PI score and the indirect impact of fidelity on post-intervention self-reported PI score mediated by post-intervention self-reported PACS score. Bootstrapped CIs (10,000 replications) were calculated for the indirect effect. As the effects of fidelity reported above were corrected for pre-intervention PI and PACS scores, self-reported pre-intervention scores for both PI and PACS were included as covariates in the mediation analysis. Only those service users who attended at least 8 out of 12 sessions were considered for this analysis ($n = 93$).

There was a significant direct effect of fidelity on PI ($t = 2.95$, $p = 0.004$), which was comparable with the total (direct plus indirect) effect of fidelity on PI ($t = 3.07$, $p = 0.003$). However, the indirect effect from the bootstrap analysis was not significant [mean (SEM) = 0.013 (0.019); 95% CI = –0.010 to 0.080]. As there was no evidence for significant mediation, we conclude that the effect of fidelity on PI scores is independent of the effect on PACS scores.

What do high- and low-fidelity lay therapists do differently?

The relationship of fidelity to self-rated PI must arise out of some specific input that is provided by high-fidelity but not by low-fidelity lay therapists, and if this relationship is independent of the acquisition of coping skills (PACS), then it may relate to aspects of the intervention that are not directly related to skills training. In order to identify aspects of the intervention that were associated with the fidelity of delivery, the 27 groups for which fidelity-monitoring data were available were divided into three sets ($n = 9$) corresponding to the groups that achieved the highest, middle and lowest fidelity ratings. The high- and low-fidelity groups were then compared for the presence or absence of each MAGIC item. All 30 items were observed more frequently in the high-fidelity groups, but the difference varied between items.

The eight items that differed most in frequency between high- and low-fidelity groups are shown in *Table 59*. Two of these items (1.ii and 5.iii) concerned delivery of the agenda for the session. However, the other six items, which included the four items that discriminated best between high and low fidelity, were related directly to the emotional content of the intervention, including explaining the rationale for group activities (5.i), working with service users' experiences (7.1, 8.i, 8.iii), and promoting trust (9.i, 9.iii).

It appears, therefore, that lay therapists who achieved a high level of fidelity in delivering the intervention differed primarily from those who did not in creating an environment in which service users felt comfortable in discussing their emotions. They may, as a result, have become more aware of and more accepting of their feelings of anger, and therefore more willing to report them.

What is the meaning of the self-reported Provocation Index score?

As reported in *Chapter 3*, pre-intervention self-reported PI scores were strongly associated with other measures of mental health, particularly anxiety (for which $r = 0.335$). However, if service users who work with high-fidelity lay therapists feel more comfortable talking about their feelings of anger then it would follow that they should be less anxious when doing so.

This prediction was tested by examining the correlation between post-intervention self-rated PI and pre-intervention GAS scores in the service users from the nine highest-fidelity and the nine lowest-fidelity

TABLE 59 Manualised Group Intervention Checklist (MAGIC) items discriminating between high- and low-fidelity groups[a]

	Fidelity			
Item no.	High (%)	Low (%)	High–low (%)	Item
5.i	83	6	77	Explained rationale and requirements for the different activities/elements of the session clearly
8.iii	78	12	66	Made the link between the emotions members expressed in sessions and their particular problems
9.i	100	35	65	Encouraged a sense of responsibility and mutual respect among group members
8.i	89	29	59	Acknowledged the emotions of the members in the course of the session
1.ii	72	18	55	Agenda was adhered to during the session
5.iii	83	29	54	Responded to seemingly irrelevant interruptions in an effective yet diplomatic manner
7.i	100	47	53	Elicited (or responded to) specific thoughts, assumptions, images, memories, beliefs or perceptions
9.iii	100	53	47	Promoted an atmosphere of collaboration between therapists and group members

a The table shows the eight MAGIC items that showed the highest discrepancy between the nine groups for which the highest and lowest levels of fidelity were recorded. The figures under high fidelity and low fidelity show the percentage of sessions in which the item was recorded as present; the column 'High–Low' shows the differences between the high- and low-fidelity values.

groups. As predicted, the correlation was highly significant in the low-fidelity groups but non-significant in the high-fidelity groups [low fidelity: $r(46) = 0.545$, $p < 0.001$; high fidelity: $r(39) = 0.172$, non-significant; difference: $p = 0.052$, two-tailed]. So, self-rated PI was strongly related to anxiety in the low-fidelity groups but in the high-fidelity groups, PI ratings were independent of anxiety. This would appear to support the conclusion that service users in the high-fidelity groups found reporting anger less anxiety provoking.

The interpretation of these results is complicated by the fact that a similar difference between the low-fidelity and high-fidelity groups was also present in the correlation between pre-intervention self-rated PI and GAS scores [low fidelity: $r(51) = 0.445$, $p < 0.001$; high fidelity: $r(44) = 0.113$, non-significant; difference: $p = 0.085$, two-tailed]. A likely explanation may be that not only are high-fidelity therapists able to create an environment where service users are comfortable in discussing their feelings, but also this is a characteristic of the centres in which high-fidelity therapists work.

Clinical psychologists' predictions

As already reported in *Chapter 5*, there was a significant relationship ($\chi^2 = 28.2$, $p < 0.001$), in the predicted direction, between supervisor predictions of outcome and overall fidelity ratings: median (IQR) fidelity scores were: predicted best, 74.6 (68.0 to 83.3); predicted intermediate, 72.4 (63.3 to 77.6); and predicted worst, 56.0 (44.8 to 71.1).

Pre- and post-intervention scores on clinical outcome variables, based on complete-case pre–post data, are shown in *Table 60*. Post-intervention scores were analysed by multilevel analysis of covariance, controlling for pre-intervention scores. Self-reported PI scores were somewhat higher (by 16.8%) in the predicted-best groups compared with the predicted worst groups but the difference was not significant [$F(2,20.9) = 1.28$, $p = 0.30$]. Both self- and key worker-rated PACS scores were also non-significantly higher in the predicted-best groups [by 28.9% and 25.8%: $F(2,20.1) = 1.97$, $p = 0.17$, 1.67, $p = 0.21$, respectively]. A minimal difference was seen for key worker-rated PI scores [$F(2,21.7) = 0.06$, $p = 0.94$].

Appendix 6 contains an account of the clinical psychologists' reflections on their experience of supervising the lay therapists and the basis for their predictions of clinical outcomes.

TABLE 60 Clinical psychologists' predicted outcomes

	Predicted outcomes		
Assessments	**Best**	**Intermediate**	**Worst**
Pre intervention			
Self-reported PI	44.3 (17.8)	43.7 (19.1)	43.9 (18.3)
Key worker-reported PI	32.7 (14.2)	35.0 (14.0)	32.5 (12.4)
Self-reported PACS	26.3 (14.9)	26.2 (15.7)	25.1 (19.0)
Key worker-reported PACS	14.0 (11.7)	14.8 (12.8)	15.7 (8.3)
Post intervention			
Self-reported PI	45.1 (17.8)	43.8 (20.0)	38.6 (19.9)
Key worker-reported PI	30.0 (14.2)	31.9 (14.4)	29.3 (11.6)
Self-reported PACS	37.0 (16.31)	39.1 (21.08)	28.7 (22.12)
Key worker-reported PACS	23.9 (12.28)	23.0 (13.36)	19.0 (13.51)

Values are means (SD).

Chapter 10 Discussion

Summary of outcomes

The intervention programme was orientated primarily to behaviour change (i.e. a more adaptive response to anger-provoking situations) rather than to reduction in anger per se. Fidelity monitoring confirmed that the programme was broadly delivered to an adequate standard, and revealed that the behavioural elements of the programme were delivered more effectively than the cognitive elements, which were formally introduced only towards the end of the intervention.

We did not find a significant impact on the primary outcome, self-reported PI scores, although there was a tendency for PI scores to decrease, more so at the 16-week follow-up assessment, and particularly when the analysis was adjusted to take account of compliance with the intervention. However, there was a significant impact on another self-rated measure of anger, the PACS-IPT. The difference between the measures is that PI anger ratings are responses to hypothetical potential triggers, whereas PACS-IPT anger ratings are responses to actual triggers that are known to make the person angry.

In line with the behavioural orientation of the intervention, significant impacts were found on anger coping skills (in terms of both self- and key worker-rated PACS scores) at both 16-week and 10-month follow-ups. Key workers and home carers also reported decreases in challenging behaviour at 16 weeks. These were maintained at the 10-month follow-up, but spontaneous changes in the control group resulted in the difference between the groups being no longer significant.

There was no significant impact on mental health, self-esteem or quality of life.

Complier-adjusted causal effect analyses in relation to the above outcomes tended to increase effect sizes where differences were significant but in general did not change non-significant findings into significant ones.

Higher service user IQ, lower depression scores and higher self-esteem scores were associated with decreased key worker PI scores. Younger lay therapists were associated with decreased self-rated PI scores and female lay therapists with increased self-rated PACS scores. The number of sessions attended was associated with decreased self-rated PI scores. Higher intervention fidelity was associated with increased self-rated PI scores; with this exception, the associations were as predicted.

Most of the service users interviewed could describe the purpose of the group and emphasised the therapeutic value of sharing experiences, the opportunity to talk about problems and the acquisition of coping strategies that they had used successfully, particularly behavioural strategies such as ‘walking away’ or ‘asking for help’. They described improved relationships with peers and a pride in what they had achieved.

Lay therapists who were interviewed welcomed the opportunity to develop their professional skills and believed that the training, the manual and ongoing supervision equipped them well to run the groups, and that they had insights into what made the groups work. Challenges they described included engaging with service users differently to their normal role and dealing with emotive issues or disclosures of a sensitive or distressing nature.

When interviewed before the intervention, managers welcomed the opportunity to develop their service and benefit from the staff training on offer. When interviewed after the intervention, they were unanimously positive about hosting the intervention and its impact on service users and staff.

The excess cost of intervention over treatment as usual was £12.34 per person per hour, which means that an intervention comprising 12 2-hour sessions would cost about £296 per person to deliver. Although the mean adjusted difference in total costs of health and social care was lower for the intervention group by £22.46 per person per week (an amount almost equivalent to the weekly excess cost of the intervention), the difference was not statistically significant.

Strengths and limitations

The study had a number of strengths, particularly in relation to earlier work in this field. We can also identify some limitations.

Strengths

A particular strength was the use of a cluster randomised control design implemented mainly within community services. People who have intellectual disabilities have often been excluded from trials of psychological therapies[156] and the viability of RCTs with this population has been questioned.[146] This study has demonstrated that it is possible to obtain evidence about the effectiveness of interventions using a randomised design applied in typical service settings and delivered by non-specialist service staff. One of the barriers to carrying out such trials has been the problem of obtaining sufficiently large samples. The design implemented here allowed clusters of individuals to be recruited and retained efficiently. It also controlled for contamination from the intervention to the control arm of the study by the clear differentiation of experimental conditions across geographically dispersed centres.

The design also improved on earlier studies (see *Table 1*) in other respects:

- The study was more than double the size of the largest published study.
- It involved a widespread replication across many teams of therapists (14 in the RCT and 24 in the pre–post study).
- Allocation to groups was fully randomised and followed completion of the baseline assessments, to avoid recruitment of different populations.
- The intervention was manualised and fidelity of delivery was monitored as part of a thorough process evaluation.
- A comprehensive assessment was implemented, which included two measures of anger expression, a measure of anger coping, and multiple measures of mental health and challenging behaviour.
- Data were obtained from both first-person and third-party respondents.
- There was clear separation between study personnel involved in data collection and intervention delivery.
- Data collectors were blind to group allocation (although this may have been compromised by incidental comments from respondents during data collection).
- Generalisation to the home environment was assessed.
- There was long-term (6 months post intervention) follow-up of both the intervention and the control groups, prior to the delivery of the intervention to the control subjects.
- Data analysis was based on regression methods using baseline score as a covariate, rather than change scores, and normality was achieved, through the use of transformations where necessary, in virtually all analyses.
- A mixed methodology was used: in addition to the quantitative assessments, interviews were conducted with service users, lay therapists and service managers to assess the impact of the intervention; we are unaware of any other study of psychotherapy outcomes that has included qualitative data from all three of these stakeholder groups.
- The study included a health economic evaluation, which was based on a total package costing approach and used non-parametric bootstrapping, while still taking account of clustering.

- The study involved the development of novel instruments: the MAGIC was developed to monitor the fidelity of intervention delivery; a self-report version of the PACS was developed so that service users could rate their own anger coping skills; and the PACS-IPT enabled service users to rate their anger in response to actual situations known to trigger anger for each individual respondent.
- A pre–post study following intervention in the control group maximised sample size for an exploration of factors associated with successful implementation.

We will amplify on a number of these points later in this chapter.

Limitations

Primary outcome measure

A major limitation of the study is that the intervention did not have an impact on the primary outcome, self-rated PI. This differs from the significant improvement that was found in other measures of anger expression, anger coping and challenging behaviour. The lack of significant change in self-rated PI scores is also inconsistent with previous outcome evaluations, which, generally – although not always[157] – have found significant decreases in self-ratings on the PI or similar instruments (see *Table 2*).

One potential reason for the difference in results between this and earlier, psychologist-led interventions is that the stated aim of the intervention, as expressed through the manual and through supervision, was to provide service users with a repertoire of coping skills that they could deploy in situations that provoke anger, rather than to decrease feelings of anger per se. Indeed, the legitimacy of anger in many circumstances was emphasised. This emphasis on behavioural rather than cognitive and emotional change was then accentuated by lay therapists rarely taking up opportunities to explore cognitive or emotional material that arose during the course of the intervention. If there was less attention to emotional responses than in previous studies, perhaps because the intervention was delivered by inexperienced lay therapists rather than by trained psychologists, then the limited extent of change in self-rated anger may reflect a corresponding underdevelopment of emotional understanding or insight. That this might be so is suggested by the discrepancy in results between the self-rated PI and the self-rated PACS-IPT. The PI requires greater perspective-taking skills, as it is based on hypothetical situations that need to be imagined, whereas the PACS-IPT is based on actual, personal experience, and the limitations of intellectual disability might amplify the contrast between responding to hypothetical and actual situations. Given the behavioural orientation of the intervention, group participants may have learned enough to register change on the cognitively simpler measure but not on the more cognitively demanding measure. For these reasons, we now have less confidence than at the outset that the self-rated PI was the ideal outcome measure for this study. This issue receives further discussion below.

Sources of bias

The preferences and expertise of the research team have been reported to have a powerful effect on the outcome of psychotherapy studies.[158,159] We acknowledge that the present investigators have a strong allegiance to the intervention, given that some of us were instrumental in its development. In an attempt to address this potential source of bias, a rigorous separation was imposed between the intervention and its assessment, such that the research assistants responsible for the assessment had no other contact with the groups that they were assessing. However, although the assessors were, in principle, blinded to group allocations, it often became apparent to them in conversation with service users and staff during the post-intervention assessments whether or not a group had received the intervention. Although allegiance to the CBT model played no part in the recruitment of the assistants, we cannot exclude that some of the investigators' enthusiasm may have rubbed off on them and that this could have had some influence on the assessment responses provided by service users and carers. However, the fact that significant or near-significant changes were seen on all anger measures but on none of the mental health measures, and on almost all of the key worker measures but on only one of the home carer measures, suggests that any such influence was at worst marginal.

A number of methodological limitations may have influenced the outcome of the qualitative studies. It has been suggested that interviewer experience and background can influence outcomes in qualitative studies.[160] Although qualified clinical psychologists, the interviewers had relatively limited experience in conducting qualitative interviews. Other psychological processes may also have influenced the course of the interviews. Some people with intellectual disabilities may be reluctant to express opinions[161] or may be more acquiescent and prone to responding in a socially desirable manner,[162] a problem that increases with level of intellectual disability.[163,164] It is therefore possible that the service users who were interviewed were reluctant to express more negative opinions about the group, or indeed their own progress within it. Service users appeared keen to present themselves positively during the interviews and achieved this in various ways, including minimising their difficulties with anger management, presenting these difficulties as historical, or highlighting their successes and achievements during and as a consequence of the group. It is possible that participants presented themselves positively in order to maintain or enhance their self-esteem. This problem is less likely to have been present in relation to the lay therapists or service managers who were interviewed but it cannot be ruled out entirely.

Logistics

Perhaps inevitably in a trial of this size and complexity, we encountered some logistical difficulties. For example, some centres found it impossible to work to the planned timetable, with the result that some of the 16-week follow-up assessments were conducted before the group had ended or, in one case, even before it had begun. There was also a loss of some centres; however, this particularly affected the pre–post study, with 14 out of 15 centres in each arm of the main trial completing the 10-month follow-up. Owing to staffing changes, it was not possible to ensure consistency of respondents for the key worker or home carer follow-up assessments. The absolute number of key worker assessments was maintained within the planned 80% retention window. However, for home carers, fewer were recruited and fewer were retained, with the result that only 60% of the planned number of 10-month follow-up assessments could be conducted with home carers, decreasing the power of the home carer analyses. This factor may contribute to the observed discrepancies in terms of statistical significance between key worker and home carer outcomes.

Clinical significance

A further limitation of the study is that no cut-off has been developed for the PI (or other rating scales) to define what constitutes a clinically problematic level of anger. Instruments such as the PI are used as part of the clinical assessment of anger, and to measure change, but the decision about clinical 'caseness' is made on the basis of a holistic clinical assessment. Therefore, it is not possible to infer the clinical significance of, for example, a 10- to 15-point decrease in key worker-rated PI scores, as seen in some groups. Similarly, there are no defined normative clinical criteria for the acquisition of anger coping skills. There does exist a clinical cut-off for challenging behaviour, according to which there appeared to be a very large decrease in challenging behaviour as reported by home carers at the 10-month follow-up, but the reliability of this observation is compromised by the low numbers of participants displaying severe challenging behaviour and a lack of stability of this measure in the control group.

Discussion of findings

Outcomes for service users

The difference between service user and key worker responses on the PI may reflect the different basis for first-person and third-party PI ratings. Anger is conceptualised as an emotion with internalising (emotional and cognitive) and externalising (behavioural) components.[28,29] Analysis of the baseline data established that service users' self-ratings of anger were related to other self-ratings of mental health status, whereas carers' ratings of service user anger were more strongly related to their ratings of challenging behaviour. As has already been discussed, the present intervention was aimed primarily at eliciting behavioural change, which was apparent to key workers. It is consistent with the cognitive model[165,166] that behavioural change may precede cognitive and emotional change. Hence, an increase in either the quality or the quantity of the intervention may be needed to achieve optimal change involving a decrease in anger expression, particularly in relation to hypothetical situations.

Key workers and home carers both reported that the intervention decreased challenging behaviour. It is well established that aggressive challenging behaviour can be minimised if staff implement appropriate behaviour management methods.[167,168] But we are dealing here with service users' own self-management of challenging behaviour. A small case series suggested that participation in anger interventions decreased both challenging behaviour and scores on the Anger Inventory, a measure similar to the PI, and that there was a significant relationship between change in these two scores.[169] However, there was no significant effect on challenging behaviour in the only previous controlled trials of anger interventions where this was evaluated.[16,46] To the best of our knowledge, this is the first controlled study to report improved self-management of aggressive challenging behaviour by people with intellectual disabilities.

Service users and key workers both reported significant improvements in the use of anger coping skills following the intervention. While these reports might reflect the acquisition of terminology rather than changes in the service users' behaviour, we think that this is unlikely, for several reasons. First, increases in the use of anger coping skills were reported not only by service users, but also by their key workers, who had not been present in the group sessions. Second, service users and lay therapists provided examples of the actual usage of anger management skills in their interviews, and lay therapists also discussed this extensively in supervision. Third, challenging behaviour decreased, presumably as a result of the deployment of anger management skills, and this was also reported in the home environment. Taking these lines of evidence together, we are confident that service users' reports of increased usage of anger coping skills reflect the genuine acquisition and utilisation of anger coping skills rather than a verbal response to interview demands.

In absolute terms, the magnitude of the improvement in PACS scores was similar for service users and key workers, but larger than the improvements reported by home carers. There are at least four factors that could account for a lower impact in the home environment. First, home carers were a more diverse group, including both paid and family carers, and these two subgroups may differ in the quality and duration of their relationships with service users. Second, anger was identified as an issue within the day-service context and for some service users may not have been seen as a problem at home (as was identified by some of the family carers in their feedback session). Third, in a previous study that reported good generalisation from day service to home carers,[48] communication with home carers was strongly encouraged. In the present study we did not record whether or not there was communication between the two environments so we cannot comment on the extent to which this took place. Finally, lay therapists were, however, strongly encouraged in supervision to disseminate information about the group within the day service, so that key workers could support service users to implement anger management skills. As a result of this communication between staff members and with service users, key workers would therefore be more likely than home carers to notice and remember instances when the skills were or were not used. This would be consistent with an earlier observation that service user and carer anger ratings were significantly correlated only after they had attended an anger management group together.[116] Nevertheless, despite the apparent failure to generalise the use of anger coping skills to the home environment, home carers did report decreases in challenging behaviour, so the absence of generalisation may to some extent reflect on home carers' perceptions rather than service users' behaviour.

Magnitude of the effects achieved

Although the intervention was successful in decreasing anger and increasing the acquisition of anger coping skills, the effects achieved by lay therapists were more limited than those reported in previous studies, with less generalisation to the home environment and smaller effect sizes. As reviewed in *Chapter 1*, effect sizes in earlier studies were typically large or very large, with a mean effect size of 1.19 (see *Table 2*). None of the effects observed in the present study was of this magnitude.

The aim of this study was to integrate the intervention into routine clinical practice. One consequence of this strategy was that we did not specify a level of anger as an inclusion criterion, as in clinical practice this decision would be made on the basis of a holistic assessment rather than a score on a particular instrument. Neither did the inclusion criteria refer to the extent to which staff found if difficult to support the service user. This low threshold for referral to the group led to the inclusion of some service users who reported very low levels of anger at baseline and who might well have been excluded from the earlier studies, which typically have been based on individuals who were directly referred to psychologists for specific difficulties with anger. Such services users might be genuinely less angry or might be less motivated to address anger issues, but whatever the reason for their low anger ratings, excluding such service users from the analysis had a minimal effect on the outcome.

There are also a number of design features of the study that may have influenced the effect size relative to earlier studies. Allocation to intervention or control conditions was strictly randomised, making equivalence between groups more likely than in earlier studies where clinical considerations may have created inadvertent biases. Also, the present results were analysed on an intention-to-treat basis, with the result that some service users were included in the analysis who received the intervention only minimally, or not at all. (However, re-analysis including only service users who were compliant with the intervention only slightly increased the effect size.) Other methodological limitations in previous studies that can lead to a bias towards an inflated effect size include the analysis of changes scores, no correction for clustering, and follow-up assessments undertaken by the intervention delivery team.

Although there are many methodological differences between this and earlier studies, a likely contributor to the smaller effects achieved in the present study is that the intervention was delivered by lay therapists, rather than psychologists. The literature in this area is inconsistent. One study found that assistant psychologists achieved smaller effects on anger than qualified psychologists.[38] However, in the most comparable earlier study, closely supervised lay therapists achieved a decrease in key worker-rated PI that was similar to those reported in psychologist-led studies, albeit that the decrease in service user-rated PI was much smaller, as here (see *Table 2*).[11] Lay therapists also achieved similar effects to psychologists in a controlled trial of CBT for depression in people with intellectual disabilities, although the psychologist-delivered intervention was shorter (5 weeks vs 9 weeks).[13,14] The present study differed from earlier studies in its breadth of replication. It included 14 separate teams of lay therapists, and outcomes varied widely between groups, ranging from no improvement or even a small deterioration to outcomes similar to, or even better than, those previously reported. Given such variability, smaller averaged effects across all groups are to be expected. Moreover, the effect sizes found in this trial might better estimate the impact of routine implementation of a lay therapist-led intervention than those found in earlier studies.

Variability between lay therapists was apparent from observation of group sessions. Most of the lay therapists were able to follow the manual and deliver the behavioural aspects of the programme, but struggled to work with service users on their emotions and cognitions, and this factor discriminated the lay therapists who achieved the highest fidelity ratings from those who achieved the lowest fidelity ratings. The psychologists who observed the groups as fidelity monitors also commented informally that lay therapists often failed to respond to opportunities to work with the group on cognitive and emotional material presented by service users, perhaps because they lacked the confidence to do so. It may be possible to assess the ability to recognise and embrace such opportunities. This information could be used to select staff with existing skills in this area or to target training to lay therapists who are less skilled.

Another factor that may be relevant to the more limited impact seen here is that the majority of the anger management techniques included in the intervention manage anger by changing the situation (e.g. walking away, help-seeking) rather than the person. These techniques represent responses to anger-provoking situations that can be very effective in limiting the build-up of anger, particularly if they become automatic and habitual.[170] However, behavioural techniques leave intact the potential of situations to trigger anger if habitual strategies cannot be implemented (e.g. a small space that prevents walking away or the absence of anyone available to provide help), and automated behavioural responses cannot be deployed when addressing questions about hypothetical situations (as in the PI). In these situations, cognitive restructuring techniques have the advantage that they have the potential to prevent trigger situations being perceived as anger provoking, and so decrease the potential for anger. As already discussed, most of the anger management techniques taught in the group were behavioural, with cognitive techniques introduced late in the programme, with little opportunity for service users to assimilate them. Consequently, and given their lack of professional training, lay therapists were also observed to overlook opportunities to work cognitively with service users. The manual did not ask them to do so until late in the programme, and the training they had received did not prepare them to recognise these situations as opportunities for therapeutic input. More experienced therapists might have been more ready to take advantage of these opportunities.

In addition to the lay therapists' limited ability to work with service users on their emotions and cognitions, another feature of the manual may have mitigated against change on our primary outcome measure, self-reported PI score. Lay therapists were instructed to emphasise to service users that although anger should be expressed appropriately, not only is feeling angry not wrong in itself, but also it is often legitimate. Indeed, the stated aim of anger management interventions is to improve anger coping skills, not to decrease anger per se. This is an ethical imperative, as many people with intellectual disabilities have much to be angry about.[171,172] Therefore, the lay therapists' achievement in teaching anger management skills that service users were able to use was a logical impact of this approach, and their more limited success in decreasing feelings of anger cannot be characterised as a failure of implementation.

Some of the lay therapists who were interviewed indicated that they had adhered closely to the manual but found it to be overly rigid and constraining, whereas others said that they had followed the outline of the session but adapted the group activities and discussions as much as possible to reflect the individual needs and circumstances of the group members. It is possible that the larger effect sizes for self-rated anger reported in psychologist-delivered interventions – and also seen in the current 'best' lay therapist-led groups – may reflect a more flexible approach conforming to the spirit, but less bound to the letter, of the manual. Inexperienced therapists tasked with delivering a busy session plan might well lack the confidence to depart from the manual or the ability to return to it smoothly after doing so. However, we do not have data with which to test these hypotheses.

Influences on outcome

A number of factors were identified that were associated with the extent of change in the main clinical outcome measures. With one notable exception – a positive correlation between fidelity and self-rated PI scores – all of the hypothesised relationships were supported. However, each of the significant effects related to only one of the outcome measures, so their implications for the overall success of the intervention are limited.

Fidelity and the interpretation of self-rated Provocation Index scores

The positive correlation between fidelity and increase in self-rated PI in this study conflicts with the finding from the general psychotherapy literature that higher fidelity of intervention is typically associated with greater effectiveness.[62,63] The therapeutic relationship has been repeatedly identified as the single most effective element in successful outcomes.[139–142,173] As has already been discussed, the extent to which lay therapists enabled service users to be open about their emotions reliably discriminated those who achieved the highest fidelity ratings from those who achieved the lowest fidelity ratings. In other words, higher fidelity was associated with the creation of a more supportive environment for service users to discuss their feelings, implying a stronger therapeutic relationship. There are good reasons why service users may be reluctant to talk about their feelings of anger, as their history of anger problems is likely to be associated with feelings of regret or shame,[174] the experience of being reprimanded and worsening relationships. Hence, particularly trusting relationships may be necessary for service users to be more open about expressing their feelings of anger.

It is possible, therefore, that higher self-related PI scores were linked to higher fidelity because individuals within higher fidelity groups had more opportunities to discuss their feelings and felt encouraged to do so, and as a result became less reluctant to admit to feeling angry. This led us to explore whether or not there was a relationship between self-rated PI score and anxiety that also differed between high- and low-fidelity groups. Self-rated PI scores were strongly associated with levels of anxiety in groups that were delivered with low fidelity, but independent of anxiety in groups that were delivered with high fidelity. Interestingly, this relationship was present even before the intervention, suggesting that it may be a characteristic of the centre rather than the lay therapists, reflecting an organisational culture that is more or less conducive to therapeutic engagement.[175,176]

These results suggest that the subjective meaning of the service users' PI ratings may be different in different circumstances. In an environment where service users feel uncomfortable about discussing their emotions openly they may feel more remote from the materials, and find it difficult to imagine themselves in the situations described in the PI, resulting in fewer reports of anger. In contrast, in situations where the service users are more comfortable about discussing their feelings, and engage emotionally with the hypothetical situations that are presented to them, they might be more likely to find the scenarios provocative and be willing to report their resultant feelings of anger. Psychologists experienced in using the intervention might be expected not only to increase engagement with anger issues, but also to work cognitively with service users to decrease the emotional impact (as reported in most earlier studies). Hence, either an increase or a decrease in self-rated PI could be a 'good' therapeutic outcome, in different service users at different stages of the therapeutic process. The responses of service users who have experienced different therapeutic environments should be more similar when reporting their actual anger experiences, using the PACS-IPT, as distinct from their ratings of imagined situations using the PI. Also, a greater openness to engaging with provocative scenarios within sessions might motivate a greater willingness and ability to work on acquiring coping strategies, so explaining the otherwise perplexing correlation between self-rated PI and PACS scores. Such an analysis of course creates even greater uncertainty about the appropriateness of self-rated PI as the primary outcome for this trial.

The 'dose' effect

The number of sessions attended was significantly associated with a decrease in self-rated PI scores but not with changes in any other measure. This is consistent with the finding from a meta-analysis of anger intervention studies that the 'dose' effect in anger interventions is relatively small.[64] Two factors that may be responsible for the limited 'dose' effect in the present study are that most of the participants received what should be an adequate 'dose' (eight or more sessions), and that the intervention involved not only the group sessions, but also a context for ongoing contact between service users and lay therapists outside of sessions. However, as service users who attended fewer than eight sessions tended to drop out early in the programme, the finding of a relationship with self-rated PI is consistent with (a) the relatively late introduction of emotional/cognitive elements of the intervention and their low incidental coverage in the early stages, (b) the interpretation that we have advanced that self-rated PI is an intellectually more demanding measure than the PACS-IPT and (c) the implication that extending the number of sessions may produce a more rounded outcome to include a decreased anger response to hypothetical situations, as typically observed in psychologist-delivered interventions.

Intellectual ability

The factor that has occasioned the greatest debate in relation to anger outcomes is intellectual ability.[12] Three studies[39,41,42] have reported that more intellectually able service users had better self-reported outcomes on the PI or equivalent measures, although there was inconsistency in the detail of these effects, whereas a fourth study[49] did not confirm this relationship.

The present data support an effect of intellectual ability on post-intervention key worker-rated PI scores. However, although there was a reliable effect of IQ on key worker-rated PI score, the effect was weak: it was present in the regression analysis (see *Table 58*), after taking many other variables into account and, despite the large sample size, only at a marginal level of statistical significance ($p<0.04$). The effect was not significant in the correlation analysis (see *Table 57*) and there was also no relationship between PI scores and receptive language ability (BPVS) in either analysis. We conclude that, although there does appear to be a small effect of intellectual ability on one key worker-reported outcome of this anger management intervention, it is unlikely to be of clinical significance. This does not mean that there is little or no influence of IQ on the outcome of anger management interventions generally, only that IQ was of minimal importance within the limited IQ range of the present participants. Different results might be obtained in a study sampling the wide range of IQs that would typically be encountered within the general population.

Mental health

A more critical factor may be the service user's mental health status. The participants presented with extremely high levels of mental health problems. High levels of depression and low levels of self-esteem have been reported to predict a poor prognosis for anger management in the general population[151] and the present results confirm these relationships for people with intellectual disabilities. Again, this was found in relation only to key worker PI ratings and not self-ratings. High levels of depression were also associated with poorer anger coping, in both control and intervention groups. The anger management intervention did not decrease levels of reported psychopathology. It is often assumed that anger shown by people with intellectual disabilities is an atypical presentation of an underlying depression.[177] However, this view has been disputed.[178] The fact that the anger interventions did not alleviate depression argues for the independence of these two conditions.

It is a matter of particular concern that few if any of the participants who were identified as achieving 'caseness' for depression or anxiety were receiving psychological interventions for these problems. This suggests that, while anger is noticed by carers because it is associated with externalising challenging behaviours, and referred for professional support, the associated mental health problems do not receive the same level of attention.[137,178] There is an identified need for further training of staff who work with people who have intellectual disabilities and mental health problems, particularly in the areas of identification and treatment.[179,180]

Lay therapist characteristics

Female lay therapists produced greater increases in service user-rated PACS scores. However, this effect was only marginally significant and was not seen in relation to key worker-rated PACS scores, so is unlikely to be of clinical significance. A stronger effect was seen in relation to the age of the lay therapist: younger lay therapists achieved larger decreases in self-rated PI scores. The obvious inference to draw from this finding is that younger staff performed 'better' in the role of lay therapist. However, the unexpected relationship between fidelity and self-rated PI score casts doubt on this interpretation. Lay therapists who delivered lower fidelity also achieved larger decreases in self-rated PI scores, and it is difficult to imagine that low fidelity of delivery is associated with being a 'better' therapist. We remain uncertain how to interpret the difference in outcome on the self-rated PI between younger and older lay therapists.

Cost of intervention relative to other health and social care input

Not surprisingly, the intervention cost more to deliver than treatment as usual. The excess cost for one 2-hour intervention session per week would increase average total package cost per week at the 10-month follow-up by 2.7%. The mean adjusted cost difference was in favour of the intervention group, by approximately the same amount per person per week as the excess cost of the intervention. However, we cannot determine whether or not the excess cost of the intervention can be off-set by such savings in health and social care resource usage as the difference in resource usage between the intervention and control groups was not statistically significant.

Although power calculations were conducted to be reasonably certain of detecting clinical outcomes should they occur, the sample may not have been of sufficient size to detect a significant impact on costs. The sample for this study included people living in residential services and family homes. Health and social care costs of residential services are typically much higher than those for the family home; indeed, some residential care costs are particularly high. This cost heterogeneity was typical of both intervention and control groups, as reflected in the large SDs for cost estimates. Differences would need to be correspondingly large to be statistically significant. The lack of power in the cost analysis was exacerbated by the smaller sample size for this analysis resulting from less comprehensive data collection.

Another factor is that staffing input in residential services is generally related to the extent of service user challenging behaviour. However, linking staff allocation within group services to individuals is difficult. Staffing establishments are often not individualised and, even if they are, staff input to service users in practice may not be the same as the theoretical allocation. Patterns of interaction between staff and service users have been assessed through direct observation[181–183] but this is complex, expensive to do and fairly impractical in a large-scale trial. The method of assessment chosen here was to establish the staffing available to all of the residents of a residential setting and adjust the share given to the participant in this study by gaining an estimate of the extent to which more or less staff resource was allocated to the participant than to other people living in the setting. While this introduced a degree of sensitivity to potential change in staffing allocation as a result of the intervention, it was nevertheless a relatively crude measure. It remains a methodological challenge to assess changes in staffing given to an individual as a result of change in that individual's behaviour.

For these reasons, the absence of apparent impact of the intervention on subsequent health and social care costs may be less clear cut than the lack of statistical significance implies.

Development of novel instruments

Three novel instruments were developed during the course of the study.

The MAGIC was developed because there was no existing instrument that was suitable to monitor the fidelity of delivery of a group-based CBT intervention for people with intellectual disabilities. Observers recorded high levels of inter-rater reliability, both overall and for most of the individual items. Inter-rater agreement was also high for global ratings of fidelity to the manual, group process, the principles of CBT, and an overall rating. The scale had good internal consistency, and principal components analysis was consistent with a single-factor solution. A wide range of scores was recorded for the fidelity of delivery of the intervention by different groups: one very low fidelity rating (19%) was awarded, whereas the other groups varied between 40% and 86%. Fidelity ratings predicted two key outcomes of the intervention, anger ratings and the acquisition of anger coping skills, and were themselves predicted by the clinical psychologists supervising the intervention. We conclude that the MAGIC is a reliable and valid instrument that is easy to use and provides information about delivery that can be used to improve the intervention. As the wording of the MAGIC is not anger specific, it should be usable in other areas of manualised group work. It could also be adapted relatively easily for individual work but would need further development for this purpose.

The PACS was originally developed as an instrument for third-party ratings by carers of the skills that service users deployed to manage anger.[11,48] The service user version of the PACS is novel. The self-rated version differs from the third-party version in having a shorter rating scale (three points vs four points) and more service user-friendly explanations of the different skills. Service user and key worker PACS ratings were not significantly correlated before the intervention but were significantly correlated afterwards (controlling for baseline scores), suggesting that the validity of the service user version may be relatively low at baseline, when the service user has a relatively low skill base, but increases after the service user has received training to acquire a set of skills, and perhaps through discussion has gained a mutual understanding of these issues with the staff member. The similar effects of the intervention on self- and key worker ratings at the levels of both the individual (see *Chapter 9*) and the group (see *Chapter 6*) demonstrate that people with intellectual disabilities are able to report accurately on their own coping behaviour, and also supports the validity of the service user version of the PACS.

Another feature of the service user PACS is that it asks service users to report on the extent to which each of the three PACS scenarios is anger provoking. This IPT provides an alternative measure of service users' self-rated anger. The PACS-IPT is based on more elaborate scenarios than PI items, and is personalised to the individual service user. Both of these features may be important, especially in relation to participants with cognitive limitations. The original IPT[47] is not personalised but was associated with a substantially larger effect size for individual anger treatment (Cohen's $d = 2.2$) than the PI or other outcome measures. Another very large effect (Cohen's $d = 2.8$) was seen using a personal diary-based measure of anger.[40] The PACS-IPT may represent a more suitable self-rating measure than the PI, particularly for people whose intellectual limitations make it difficult to imagine hypothetical situations. Although the PACS-IPT needs further development, it clearly shows potential as an alternative, and perhaps superior, measure of the response to actual provocations that the individual service user encounters. However, in its present form the PACS-IPT is a relatively crude scale and further development is needed to provide a more differentiated outcome measure.

Use of mixed methodology

Qualitative methods have previously been used to explore the experiences of people with intellectual disabilities across a variety of situations, including transition from the family home,[184] parenthood,[185] and as users of various services, including day services[161,186] and health services.[187,188] However, research concerning the health of people with intellectual disabilities has primarily focused upon the epidemiology and clinical presentation of health difficulties, or upon the outcomes of interventions. There remains a relative paucity of information regarding the experiences and opinions of individuals with learning disability who have engaged with health services or interventions, including those delivering psychological therapies. Yet, information about the lived experiences of this group of service users might guide the development and design of psychological therapies and significantly enrich and complement the data described in quantitative studies. We are aware of only three published studies of the experiences of engagement in psychological therapies by people with intellectual disabilities,[189–191] only one of which was concerned with CBT.[190]

Mixed methods research holds out the prospect of a holistic understanding of process and outcome that if successfully implemented should enrich the understanding of both the qualitative and the quantitative components.[192–194] The use of a mixed methodology in the present study has enriched both the qualitative and the quantitative components. To the best of our knowledge, this is the first trial with people with intellectual disabilities to integrate process and outcome analyses.

Most obviously, the uniformly positive response from service users, lay therapists and service managers supports the conclusion that although the quantitative outcomes of the trial were in some respects modest, they were nonetheless clinically meaningful. In particular, the negative result on the primary outcome measure is out of line not only with the other quantitative data, but also with all of the qualitative data. Hence, the qualitative findings support the conclusion that emerges from the quantitative analyses that the self-rated PI may be unreliable as a measure of felt anger. We were able to use the qualitative data to develop a tentative interpretation of the positive relationship between treatment fidelity and PI scores. This informed a further exploratory quantitative analysis, leading to the conclusion that PI scores may have a different meaning in more supportive compared with less supportive therapeutic environments.

A second major area of cross-fertilisation is in relation to the potential roll-out of this intervention. The qualitative data support the acceptability of the intervention across all three constituencies of service users, lay therapists and service managers. Service users greatly enjoyed the group, lay therapists overcame their initial anxieties, and service managers were enthusiastic to repeat the experience. It was clear from interviews with service users and lay therapists that the behavioural components of the intervention had the greatest resonance with both sets of participants. It was also clear from the interviews that the quality of social relationships developed in the group, both between group members and between service users and lay therapists, appeared to be of paramount importance for achieving clinical change. However, a quantitative analysis of fidelity to the intervention narrowed the focus to a particular aspect of social relationships, the ability of lay therapists to create a therapeutic environment where service users felt comfortable to talk about their emotions. A qualitative study of individual CBT similarly reported that participants valued the opportunity to talk about their problems, experienced the process of being listened to as validating, and were helped by positive therapeutic relationships characterised by warmth, empathy and ease.[190] This has implications for the selection, training and supervision of lay therapists, as discussed further below.

Wider impacts of the intervention

The qualitative interviews provide further insight into the process of change. It was clear from service users' statements that certain activities had been particularly memorable for them, and their accounts often conveyed their enjoyment of such activities. The themes captured the participants' lived experiences of taking part in the group, and the wider impact of participation. Most of the accounts concerned behavioural techniques which may be more easily described (and recalled) than (more abstract) cognitive ones. It is also important to note that the intervention manual stressed the behavioural components more and that, therefore, the participants had been exposed more to them and this was supported by the fidelity monitoring of sessions. It has been suggested that some individuals with intellectual disabilities might be reluctant to express any opinions due to low self worth,[195] and that individuals with intellectual disabilities may be more acquiescent and prone to socially desirable responding.[196] It is therefore possible that the individuals who participated in this study may have been reluctant to express more negative opinions regarding the group or indeed their own progress. However, given the numerous examples they were able to provide, it is more likely that their positive stance in the interviews accurately reflects their overwhelmingly positive experiences. Moreover, the accounts of the lay therapists confirm that the group members had engaged enthusiastically with the task demands and not just enjoyed the experience of being in a new social setting. Indeed, the environment and the people were not novel to them, as the groups took place in the day/residential service regularly attended.

In keeping with the behavioural focus of the intervention identified in fidelity monitoring, it was clear that the active, behavioural change component of the intervention resonated most with the service users, who particularly emphasised the behavioural techniques that they had learned: for example, describing the use of their newly acquired behavioural skills, such as 'walking away' and 'asking for help' to manage feelings of anger. Moreover, those participants who did not describe use of specific strategies, or indeed memorable group activities, did not recount examples of how the group had impacted upon them, suggesting that service users linked the anger management strategies to the changes they experienced. The sense of pride that the participants expressed suggested that they perceived themselves differently as a consequence of their behavioural achievements. However, service users said little or nothing about their thoughts or feelings, and use of the more cognitive strategies introduced in the latter part of the intervention was never mentioned. We are unable to determine whether or not this reflects the participants' own difficulties in comprehending and utilising these more complex strategies, the confidence of the lay therapists in delivering these more abstract components of the programme or the shorter time available to assimilate these elements of the programme. However, adults with intellectual disabilities who received individual CBT sessions delivered by clinical psychologists in a previous qualitative study also failed to recall any specific cognitive strategies,[190] suggesting that this problem is not attributable specifically either to lay therapists or to time constraints, and may reflect the intrinsic difficult of the cognitive components of CBT for people with intellectual disabilities.

It was also apparent from the interviews that the intervention had impacts that were not necessarily captured by the quantitative outcome measures. In particular, the aspects of the group that were reported most positively by the majority of participants appeared socially focused, rather than specific to this particular intervention, and both service users and lay therapists commented on the extent to which their relationships had improved. It appeared that a particularly powerful stimulus to the improvement of relationships was provided by staff discussing their own anger problems in the group and completing homework logs. As a result of their common participation in the group, lay therapists and service users achieved a greater mutual understanding (as also reported in earlier quantitative studies[41,116,173]), service users felt understood rather than judged, and lay therapists felt that they had developed closer bonds with the service users.

There is a large literature dealing with the importance of non-specific factors in psychological therapy,[197,198] and there are very good reasons why relationships should be key to therapeutic change with people who have intellectual disabilities. Service users with intellectual disabilities rarely refer themselves for help with anger problems.[143] Consequently, they may be reluctant to accept that they have anger problems or they may be suspicious of the motives of the lay therapists, whose job as staff members is usually to discourage inappropriate expressions of anger rather than to provide therapeutic help. This means that a crucial first step for the therapists must be to overcome such concerns and build good relationships. What also makes these therapeutic bonds particularly powerful for people with intellectual disabilities is that they have considerably more restricted social networks than their non-disabled peers,[199] and far fewer relationships that might be sufficiently intimate to be confiding.[200] Moreover, service users are rarely listened to or treated as equal partners in relationships with staff members or professionals who hold positions of power in their lives.[191]

Managers and therapists commented that staff worked better with one another and with service users as a consequence of taking the lay therapist role. The active engagement of the centre staff in the therapeutic process, even if the key workers did not themselves act as lay therapists, might also have helped them to gain more insight into the service users with whom they work. Staff members' positive views about the increasing skills displayed by the service users, as shown by their PACS ratings, may also suggest that the staff perceived service users differently. Shifts in the relationships between service users and staff members might be a consequence of behavioural change, but improvements in interpersonal relationships could also engender cognitive changes, such as a reduced sensitivity to threat in particular situations that have personal salience. These changes are likely to have an impact on aspects of the organisation that will have a positive impact on therapeutic outcomes,[175] the well-being of staff,[176] and, ultimately, staff performance.[23]

In addition to the improved relationships between service users and staff, most of the service users commented on the value that they had gained from the opportunity to talk, and be listened to, and to share experiences with other service users. Although therapist-delivered interventions may offer opportunities for service users to form a relationship, and to communicate openly with another individual, these interactions are less likely than peer support to provide a basis for the development of lasting relationships. Thus, it seems likely that the group itself was an important vehicle for therapeutic change. This may be particularly salient when considering the context in which participants experienced anger. Service users who provided examples of triggers for anger all talked specifically about difficulties associated with relationships. Similarly, their accounts of using coping strategies were typically embedded in situations involving relationships and interactions with other people. A group-based intervention provided opportunities to discuss and rehearse coping strategies in a social context, and concomitant opportunities to experience positive relationships, even when discussing difficult subject matter.

The lay therapists identified a range of skills that they considered were fundamental to effective group facilitation, such as managing group dynamics, setting the appropriate conditions for a 'therapeutic environment' characterised by the forging of supportive relationships and trust while setting appropriate boundaries, and the ability to respond to individual needs (and adapt the content and flow of discussions accordingly) within a group context. The concept of 'collaboration' between the lay therapists and group members through exchange of ideas and working together captures the essence of the therapeutic relationship in CBT.[201] The fact that some participants shrugged off the label 'therapist' is of interest, as both the qualitative interviews and the quantitative outcome data indicate that they succeeded in facilitating therapeutic processes and that service users experienced therapeutic gains.

All three groups of respondents commented favourably on the way in which the group had positively influenced the organisational culture of the service. The lay therapists also expressed their personal appreciation of the training and supervision they had received, which they felt had increased their psychological insight into service users' problems and their ability to respond to them. The lay therapist role was a new and initially daunting one, but participants welcomed an opportunity to expand and diversify their existing roles in order to develop their professional knowledge and skills and contribute to service development, and ultimately to support service users more effectively. The rationale for delivering the intervention within day services was that staff would gain the skills to support service users outside the group, both during the intervention and subsequently, and all three groups of respondents commented on the value of this strategy. Although the service user and lay therapist interviews were conducted shortly after the end of the intervention, the second round of interviews with managers was conducted 6 months later. The managers' comments thus confirm that the hope was fulfilled that the lay therapists would continue to use the skills that they had learned. Perhaps the most positive endorsement of the value of the intervention was that all of the managers expressed the intention to run more groups.

Implications for service development

Involvement of staff members as lay therapists

It was clear from interviews with lay therapists and service managers that staff in day services had received little or no training in how to take a psychological approach to supporting service users who have anger problems. The services that participated in the present study catered for service users with a variety of significant challenging behaviours, and managers reported ways of coping with these challenging service users that were inappropriate, inconsistent and contradictory. It is therefore an important finding that staff members can be trained to work therapeutically to support service users to achieve beneficial clinical outcomes. Group-based CBT facilitated by 'lay therapists' was perceived as acceptable and viable by service users, the lay therapists themselves and service managers, and engendered clinically significant changes in service users' ability to cope with anger.

Acting as a lay therapist was also reported to improve the interpersonal and professional effectiveness and confidence of the staff who took on this role. The fact that the work was carried out by untrained staff, albeit under the supervision of clinical psychologists, fits well with the need to increase access to psychological therapies for disadvantaged groups such as people with intellectual disabilities, who suffer from health inequalities.[7,8,179] Several of the managers interviewed suggested that further training, accessible to more staff, would be of benefit to any service where one or more service user presents with challenging behaviours due to anger problems.

In an earlier study of individual CBT, service users with intellectual disabilities were able to identify areas of therapeutic change, but many saw change as fragile and were concerned that progress would not be maintained beyond therapy.[190] The involvement of lay therapists provides an 'in-house therapist' model of psychological service provision, as the therapists in the current study were in a position to be more permanent fixtures in the service users' daily lives and were able to provide proactive and continuous support. Staff in day services are also ideally positioned to communicate with service users' home carers to promote the generalisation of skills learned in therapy sessions to other contexts, albeit that this occurred in the present study to a lesser extent than has been previously reported.[48]

The lay therapists did not operate autonomously: they worked under the supervision of a qualified clinical psychologist. The lay therapists said that they valued supervision as an opportunity to receive advice, support and feedback when complex issues arose, for example in response to disclosures made in the group relating to risk or vulnerability. The clinical psychologists, likewise, identified lay therapist engagement with supervision as an important characteristic of groups that were delivered well. These considerations have implications for the future direction of this model of practice. The evidence of the present study is that lay therapists are able to deliver good clinical outcomes from group-based CBT for anger management when supported by a clinical psychologist. However, there is no evidence that lay therapists would be able to operate autonomously in the absence of such support. The supervision of lay therapists by psychologists fits well within the consultancy model promoted as part of the 'New Ways of Working for Applied Psychologists' initiative.[202]

Similar considerations apply to lay therapists' use of the therapy manual. Although most therapists and managers judged the manual to be reassuring, practical and time-saving, with the right amount of structure for each of the sessions, some experienced it as too rigid and wished to allow for flexibility in order to be more responsive to the particular and fluctuating needs of the group members (e.g. to discuss a topic more fully). Although such flexibility would be desirable in the hands of a more experienced therapist, it may be difficult for inexperienced therapists to work flexibly without losing elements of the intervention. In addition, some managers indicated that resource constraints might incline them to decrease the number of group sessions. Again, the evidence base developed in this study relates to the delivery of the therapy manual over 12 sessions. If future group interventions were to allow for more flexibility or fewer sessions, there would be even more need for therapists to receive sufficient clinical supervision to avoid a 'watering down' of the intervention model that has been shown to be effective, and to ensure that flexibility is used appropriately.

Selection and training of lay therapists

Group outcomes were highly variable, with some lay therapists achieving outcomes that are similar to those in the published literature, whereas others provided little or no benefit. It is certainly possible that this variability to some extent reflects service user differences. (For example, poor mental health was associated with poorer individual outcomes.) However, it did appear that the lay therapists' ability to create a therapeutic environment within the group might also contribute to this variability. Therefore, this factor should be taken into account and assessed when selecting staff to take on the role of lay therapist. There were also differences in the extent to which organisations were amenable to a psychological way of working and supported the lay therapists to undertake the intervention, which should also be assessed and addressed. We also acknowledge that the 1-day training provided to lay therapists prior to commencing the trial was minimal. Although we have no evidence that more training would achieve better outcomes, this does seem a distinct possibility, particularly in relation to groups that achieved poorer outcomes. With hindsight, it may have been helpful to include an information session for all staff in each centre, as there was also variability in the extent to which lay therapists were able to involve other staff in supporting the intervention.

In contrast to interventions administered by psychologists, following which service users typically report decreased anger ratings, the interventions delivered by lay therapists with high fidelity to the manual were associated with increased self-rated PI scores, albeit improvement was shown on many other clinical indicators. As discussed above, this may reflect differences between lay therapists and psychologists in the ability to recognise and capitalise on opportunities to work with service users on their cognitions in relation to anger-provoking situations. It may be that with additional training, more psychologically minded[203,204] lay therapists might be enabled to grasp these opportunities. However, considering the duration of cognitive therapy training courses, it seems unlikely that much could be achieved rapidly. Perhaps this shortfall should simply be acknowledged and accepted as a limitation of the lay therapist model.

Support for mental health problems

The service users who participated in the study had very significant emotional difficulties (a high level of 'caseness' for anxiety and depression). The present trial was of an intervention for problem anger but there is no reason to suppose that lay therapists would not be able to operate successfully in other areas. Indeed, there is evidence that lay therapists can effectively deliver a manualised intervention for depression.[14]

The anger management intervention did not significantly impact on service users' mental health problems, although some improvement in depression was seen in an earlier trial of psychologist-delivered therapy.[38]

In light of these different outcomes, we recommend that service users referred for anger interventions should receive a comprehensive assessment that includes assessment of their mental health status. This should be assessed routinely before commencing an anger intervention for two reasons: because poor mental health implies that the intervention will be more challenging to administer, and because people with intellectual disabilities who present with anger may also benefit from interventions targeting their mental health. The association of anger outcome with pre-intervention mental health status also highlights the importance of basing intervention on an individual formulation that seeks to explain the link between anger and mental health problems. This was not done in the present study, with the result that the intervention decreased anger but left mental health problems unchanged.

Beyond crisis intervention

Another strength of involving staff to deliver interventions to groups of individuals, following the model used in this trial, is that it offers a more proactive approach to building the coping mechanisms of people with intellectual disabilities, rather than the usual crisis management approach that waits until individuals and their carers or family members reach breaking point. Psychopathology is common among adults with intellectual disabilities and, therefore, the capacity to provide therapeutically appropriate environments is a requirement for all organisations supporting people with intellectual disabilities.[157,175] Within these complex organisations, staff groups function within hierarchies and a variety of environments. Challenging behaviour is stressful for staff,[22,134] but their ability to cope is a function of their perceptions of self-efficacy,[152] and can be influenced by organisational factors such as supervision and support.[205] An organisational climate that has a good 'person–environment' fit promotes better job satisfaction for staff and potentially better outcomes for clients.[176] These broader organisational contexts in which therapeutic procedures for adults with intellectual disabilities are implemented are rarely considered.

The present approach, comprising a clear psychological orientation, structured through a manualised intervention with professional training and supervision, is a contribution to the wider task of building supportive environments. The group provided tools that both service users and staff could use with confidence in challenging situations. Equipping staff with skills to understand how and why challenging situations arise and to prevent rather than simply react to them has important long-term utility. The groups provided both individual and organisational benefits and managers were motivated to continue and expand the intervention. Because service managers consider the manualised group approach to be not only acceptable but also desirable, it could become integrated into the practice of an organisation, with a potential to benefit not only the individual group members but also the lay therapists and the organisational culture as a whole.

However, a note of caution is needed. Informal contact subsequent to the end of the study suggests that despite the good intentions of service managers to repeat the groups, few have actually done so, and many of the lay therapists have moved on to other posts. We are aware of only five participating services that, until now, have approached their local clinical psychology service for support to repeat the group. The development of services provided by lay therapists could constitute job enhancement and promote staff retention but external support and encouragement may be needed to achieve these objectives.

Implications for future research

Methodological issues

This study has raised some important questions about the assessment of anger in people with intellectual disabilities. It has highlighted the need to differentiate between felt anger and anger expression, and questions the extent to which the currently available instruments address these two questions. The seemingly paradoxical increase in anger (self-reported PI score), associated with greater fidelity of delivery of the intervention, clearly requires further investigation. Also highlighted is the difference between hypothetical and actual triggers for anger with the suggestion that the latter may be a more sensitive basis for detecting change following an intervention. However, as discussed, the PACS-IPT requires further development.

Although the PACS has been used in previous studies,[11,48] it was designed as a third-party report measure. The service user version of the PACS was used here for the first time. The fact that the first-person and third-party versions of the PACS were equally sensitive to change following the intervention, and the correlation between the changes reported by the two sets of respondents, adds to the evidence that people with intellectual disabilities are able to report on their own behaviour, and encourages further research that directly engages people with intellectual disabilities rather than relying on third-party reports.

The qualitative data provide a further stimulus to research that speaks directly to people with intellectual disabilities. The application of IPA to data gathered through interviewing adults with intellectual disabilities is relatively recent and under-researched. There is an extensive literature on the potential problems encountered when interviewing people with intellectual disabilities, such as the tendency to acquiesce and provide socially desirable responses and a reluctance or inability to express opinions due to inexperience, lack of assertiveness and self-esteem,[161] as well as the additional challenges for the interviewer when interpreting the verbal and non-verbal communication of a person with limited language skills.[168] In the current study the IPA procedures were adapted and piloted in order to ensure that service users were enabled to speak freely and as extensively as possible about their experiences. The resultant transcripts were judged to contain sufficient content to be suitable for IPA and have provided evidence for IPA (albeit adapted) being a suitable methodology for adults with mild and moderate intellectual disabilities.

The present results also encourage further research on therapy outcomes for people with intellectual disabilities. The viability of RCTs with this client group has been questioned[146] but the present study demonstrates that they are eminently feasible, at least using a cluster randomised design and when recruiting people capable of giving informed consent. Further controlled studies of therapy outcomes are needed, and if those studies use a manualised group-based approach, the MAGIC provides a potential tool for assessing the fidelity of delivery.

Clinical issues

The main clinical issue arising from this study is whether, or to what extent, the outcomes could be improved by modification of the intervention. We have already raised the question of whether or not the 1-day training package that the lay therapists received may have been insufficient to prepare some or all of them to deliver the intervention, but there is no information from which to determine the optimal input of training and supervision, or how to tailor these inputs to the needs of individual lay therapists. The optimal length of the intervention is also uncertain. An increase in the number of sessions would provide opportunities for consolidation, more support to less engaged group members, and extended practice of the more difficult cognitive strategies. However, this conflicts with pressure from some service managers for fewer sessions. We have observed that there may be some advantage to allowing more flexibility in the use of the manual, but this would require a level of competence and confidence that the present training package is insufficient to assure. An alternative approach could be to pair a lay therapist with an assistant psychologist (or another professional such as a community nurse with appropriate experience) as group facilitators,[48] so retaining the benefits of the lay therapist model while increasing the psychology input to the group at relatively low cost. (Like the present model, this requires the group to be supported by a clinical psychology service. There is a question of whether or not lay therapists could use the manual to deliver the intervention without psychology support, but in view of the limited clinical outcomes of many groups, and the value that the lay therapists attached to supervision, we would predict an adverse outcome.) A related research question is whether or not outcomes would be improved by more careful selection of the lay therapists, and we have suggested that psychological mindedness[203,204] might be a key issue to consider.

The lay therapists represent a second potential research focus. Service managers noted that they observed an increase in confidence, skills and knowledge in these staff members, and a willingness to diversify in their role and train other staff. Further research is needed to establish the extent to which these impacts are maintained and generalised, and the extent to which service users benefit. Potential benefits of the lay therapist role should also be assessed in relation to staff self-efficacy, job satisfaction, applied psychological knowledge and attributions of challenging behaviour, as well as organisational factors such as the therapeutic climate,[175] staff attitudes and perceptions with respect to the organisation, or staff absenteeism. The performance of lay therapists within the group is also of interest. Participants shrugged off the label 'therapist' but their accounts indicate that they worked therapeutically and service users experienced therapeutic gains. Observational studies of the group dynamics and distribution of power[206,207] during group sessions may allow more fine-grained analysis of the therapeutic process.

The present study was conceived within a framework of stepped care, in which simple but effective low-intensity and low-cost procedures, such as brief therapies,[208] bibliotherapy[209] or computerised treatments[210] are administered as first-choice interventions, with the possibility of 'stepping up' to a more intensive or expert intervention if they fail.[211] The UK IAPT programme exemplifies this approach.[5] The demonstration that lay therapists can effectively deliver manualised interventions to people with intellectual disabilities (present study) encourages the wider use of the lay therapist model. Care staff represent an untapped resource that is located in settings as diverse as, for example, care homes for older adults and prisons. The success of the present intervention, albeit modest, encourages the extension of the lay therapist model, with an associated research agenda, to other client groups, other settings and other indications.

Conclusions

1. This was the largest and the first methodologically robust RCT of any CBT-based intervention for people with intellectual disabilities.
2. Fidelity of delivery was variable, although, overall, the manualised intervention was delivered to an adequate standard by lay therapists, following brief training and with ongoing supervision from a clinical psychologist. However, their group facilitation and attention to behaviour change was stronger than their attention to cognitive and emotional change.
3. The impact on self-rated anger was equivocal, with no change in the primary outcome measure, self-rated PI, but a decrease in self-rated PACS-IPT.
4. First-person and third-party reports of anger have a different basis. Service user ratings appear to reflect their internal emotional state, whereas carer ratings appear to reflect service users' observable behaviour. The intervention significantly decreased key worker-rated PI, which may reflect a response to service user behaviour rather than internal emotional state.
5. The intervention produced clear behaviour change: anger coping skills increased according to both service users and key workers and challenging behaviour decreased according to key workers and home carers.
6. With the exception of challenging behaviour, all significant effects seen at 16-week follow-up were maintained at the 10-month follow-up (6 months post intervention).
7. There was no significant impact on mental health, self-esteem or quality of life.
8. Effect sizes for decreases in anger and challenging behaviour were smaller overall than have been previously reported, with considerable variability between groups. This probably reflects both the methodological inadequacy of earlier trials and the delivery of the intervention by lay therapists rather than psychologists.
9. There were influences of IQ, depression, self-esteem, treatment 'dose' and lay therapist characteristics on specific outcomes but no generally influential factor was found. There was an apparently paradoxical effect of higher intervention fidelity to increase self-rated PI, but this may reflect the way a reluctance to discuss feelings alters the way that people with intellectual disabilities might complete the measure.
10. People with mild to moderate intellectual disabilities are able to participate in interviews about their therapeutic experiences and also to report on their mental state through appropriately constructed questionnaires.

11. Service users, lay therapists and service manager were positive about the impact of the intervention on service users, the staff who had participated in the groups and the services as a whole.
12. There was a modest excess cost of intervention over treatment as usual. The mean adjusted cost difference was non-significantly in favour of the intervention group, by approximately the same amount as the cost of the intervention per person per week. The study may not have had adequate power or sensitivity to potential changes in staff allocation to detect change.
13. The MAGIC is a reliable and valid instrument for monitoring fidelity of manualised group-based CBT interventions for people with intellectual disabilities.
14. The service user version of the PACS is a reliable and valid instrument for adults with mild to moderate intellectual disabilities to report acquisition of anger coping skills.
15. The PACS-IPT provides an individualised measure of self-rated anger that may be more appropriate than pre-existing instruments (e.g. the PI) for people with intellectual disabilities because of its more concrete, less hypothetical nature. However, the PACS-IPT needs further development.
16. The study supports the viability of conducting RCTs of psychological interventions with people with intellectual disabilities.

Overall, we cannot conclude that the intervention was effective at reducing felt anger among service users, as there was not a significant decrease in the primary outcome measure, self-rated PI, but we also cannot conclude that it was ineffective in this respect as significant improvement on a more personally relevant measure of self-rated anger (PACS-IPT) was found. The more personalised and concrete approach of the latter measure may be more sensitive and appropriate for this population as people with intellectual disabilities have lower capacities for conceptual abstraction and generalisation. More research is required on the best methods for measuring felt anger in this population. Such research has the potential to clarify the above uncertainty over the impact of the intervention in this trial.

However, we can be more confident in concluding that the intervention was effective in increasing service users' anger coping skills. This is an important clinical outcome, which would, in itself, justify a recommendation on clinical grounds for making such intervention more widely available. It is not clear though whether or not we can make that recommendation on cost grounds. The findings on costs are promising as the baseline-adjusted cost difference at follow-up is in favour of the intervention group and of such a magnitude that there would be a fairly immediate repayment of the excess costs of intervention. Further research is needed to clarify the extent to which the cost difference found here might represent a real saving in service support costs.

If the recommendation on clinical grounds were to be pursued, this trial has shown that the manualised intervention can be delivered reasonably well by lay therapists, after a brief training and with ongoing professional supervision. Effectiveness might be enhanced, particularly in the area of emotional or cognitive change, by modest revision of the treatment orientation and manual, better selection of lay therapists, extended training, more supervision, and/or an increase in the number of sessions. However, as it stands, the trial appears to have demonstrated a means of increasing anger coping skills that could be replicated with, at worst, marginal additional cost.

Recommendations

For research

1. Further research is needed to improve the assessment of anger by people with intellectual disabilities and to understand better the relationships between self-rated anger, willingness to discuss emotions and anger coping ability.
2. Research is needed to develop optimal methods for selecting, training and supervising lay therapists and to test the impact of modifications to manual content and intervention length.
3. A similar trial is needed of anger management delivered by clinical psychologists and investigation of differential efficacy of psychologists compared with lay therapists.

4. Controlled trials of psychological interventions for people with intellectual disabilities should include a check for the fidelity of the intervention. Such trials should also routinely incorporate a process evaluation including the use of interviews and qualitative analysis.
5. Complementary studies might help clarify the impact on health and social care costs, particularly the use of staff. More sensitive assessment of outcome is required and this might be feasible in more detailed evaluation of impact in smaller samples.

For services

1. The lay therapist model should be used more widely to increase the availability of psychological interventions to people with intellectual disabilities, provided that lay therapists are supported by a qualified clinical psychologist.
2. People with intellectual disabilities referred for problems with anger control should be offered a mental health assessment in addition to an anger assessment, and the outcome taken into account in the design of the anger intervention.
3. Manualised psychological interventions for other common mental health problems in people with intellectual disabilities should be developed and implemented as a matter of urgency.
4. Clinical psychologists and other external professionals should be encouraged to develop consultancy models of working to support staff to build psychological competency within organisations and to maximise the use of scarce resources.
5. Clients should be seen as being at the centre of their psychological care. Wherever possible service users should be seen as the primary source of information concerning their psychological difficulties, with information from other sources being used to support self-report.

Acknowledgements

Contribution of authors

All of the following named authors contributed to the development of the research question and study design, study implementation (including membership of study management group), analysis and/or interpretation of data and submission of the final report. Contributions to individual study outputs/particular study contributions are denoted below in publication citations.

Professor Paul Willner (Consultant Clinical Psychologist) chief investigator, lead applicant, study guarantor; led the development of the research question, study design, study implementation and report submission.

Dr John Rose (Consultant Clinical Psychologist) co-applicant; led the development of the research question, study design, study implementation in the Midlands; and contributed to the report submission.

Professor Andrew Jahoda (Professor of Learning Disabilities and Clinical Psychologist) co-applicant; led the development of the research question, study design, study implementation in Glasgow; and contributed to the report submission.

Dr Biza Stenfert Kroese (Consultant Clinical Psychologist and Senior Lecturer) co-applicant; led the qualitative elements of the study; led the development of the research question, study design, study implementation; and contributed to the report submission.

Professor David Felce (Director of the Welsh Centre of Learning Disabilities) co-applicant; proposed the need for the trial; designed and led the health economic evaluation; led the development of the research question, study design, study implementation and report submission.

Dr Pamela MacMahon (Clinical Psychologist) collected data from service users, conducted interviews with lay therapists, service users and service managers; led the study implementation in Glasgow; and contributed to the report submission.

Dr Aimee Stimpson (Clinical Psychologist) collected data from service users, conducted interviews with lay therapists, service users and service managers; led the study implementation in South Wales; and contributed to the report submission.

Dr Nicola Rose (Clinical Psychologist) collected data from service users, conducted interviews with lay therapists, service users and service managers; led the study implementation in the Midlands; and contributed to the report submission.

David Gillespie (Statistician) carried out the randomisation process and statistical analysis, and contributed to the study implementation and report submission.

Jenny Shead (Assistant Psychologist) collected data for the Midlands region with service users, staff and home carers; contributed to the study implementation and report submission.

Claire Lammie (Assistant Psychologist) collected data for the Glasgow region with service users, staff and home carers; contributed to the study implementation and report submission.

Christopher Woodgate (Assistant Psychologist) collected data for the south Wales region with service users, staff and home carers; contributed to the study implementation and report submission.

Julia Townson (Trial Manager) led trial management; chaired project team meetings; and contributed to the study implementation and report submission.

Jacqueline Nuttall (Senior Trial Manager) contributed to the design, trial management, study implementation and report submission.

Professor David Cohen (Professor of Health Economics) contributed to the health economic evaluation and report submission.

Professor Kerenza Hood (Professor of Medical Statistics), Director of the South East Wales Trials Unit (SEWTU) co-applicant; led the study design and supervised the statistical analysis; overall responsibility for the trial management; contributed to the study implementation and report submission. Responsible individual to the sponsor for the conduct of the study.

Contribution of others

National Institute for Social Care and Health Research Clinical Research Centre (NISCHR CRC): Sarah Hunt (Clinical Studies Officer) and Vaughn Price (Clinical Studies Officer) collected data in south Wales.

Welsh Centre for Learning Disabilities, **Cardiff University:** Claire Pimm (Research Assistant) and Andrea Meek (Research Officer) collected data in South Wales.

Scottish Mental Health Network: Jacqueline McTaggart and Seonaid Cleare assisted with the data collection in Glasgow.

Glasgow University: Katie Baynham (Research Assistant) assisted with the data collection in Glasgow.

Administrative support: Mrs Sian Dawes (Trial Administrator), Vicky Roberts, Amanda Iles and Nigel Kirby.

Members of the Trial Steering Committee: Professor Glynis Murphy (chairperson), Dr Steve Noone, Dr Alan Montgomery (vice chairperson), Ray Cole, Helen Bevan, Helena Madden and Stephen Malcolm.

Institutional support: We acknowledge with thanks the trial funders, the UK National Institute for Health Research Health Technology Assessment programme (NIHR HTA). SEWTU is funded by the Welsh Government through NISCHR and the authors gratefully acknowledge SEWTU's contribution to the study.

Services and Participants: We acknowledge, with thanks, all of the services, staff and service users who participated in the trial.

We thank all those not otherwise mentioned above who have contributed to the Anger Management Trial.

Publications

1. Willner P, Jahoda A, Rose J, Stenfert-Kroese B, Hood K, Townson JK, *et al.* Anger management for people with mild to moderate learning disabilities: study protocol for a multicentre cluster RCT of a manualised intervention delivered by day-service staff. *Trials* 2011;**12**:36.

2. Rose J, Willner P, Shead J, Jahoda A, Gillespie D, Townson J, *et al.* (2013) Different factors influence self-reports and third-party reports of anger by adults with intellectual disabilities. *J Appl Res Intellect Disabil* 2013; in press.
3. Stimpson A, Stenfert Kroese B, McMahon P, Rose N, Townson J, Felce D, *et al.* Taking on the role of 'lay therapist': The experiences of staff taking on the role of lay therapist in a group-based cognitive behavioural therapy anger management intervention for people with intellectual disabilities. *J Appl Res Intellect Disabil* 2013;**26**:63-70.
4. Willner, P, Rose J, Jahoda A, Stenfert Kroese B, Felce D, Cohen D, *et al.* Group-based cognitive-behavioural anger management for people with mild to moderate intellectual disabilities: cluster-randomized controlled trial. *Br J Psychiatry* 2013; in press. DOI: 10.1192/bjp.bp.112.124529.

References

1. World Health Organization. *ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines*. Geneva: World Health Organization; 1992.
2. British Psychological Society. *Learning disability: definition and contexts*. Leicester: British Psychological Society; 2001.
3. Fletcher R, Loschen E, Stavrakaki C, First M (editor). *Diagnostic manual – intellectual disability (DM-ID): a textbook of diagnosis of mental disorders in persons with intellectual disability*. New York, NY: NADD Press; 2007.
4. Roth A, Fonagy P. *What works for whom? A critical review of psychotherapy research*. New York, NY: Guilford Press; 2004.
5. National Website for the Improving Access to the Psychological Therapies Programme. URL: www.iapt.nhs.uk (accessed 5 March 2013).
6. Office for Public Sector Information. *Equality Act*. London. 2010. URL: www.legislation.gov.uk/ukpga/2010/15/contents/enacted (accessed 5 March 2013).
7. Improving Access to Psychological Therapies (IAPT). *Learning disabilities: positive practice guide.* 2009 URL: www.iapt.nhs.uk/silo/files/learning-disabilities-positive-practice-guide.pdf (accessed 5 March 2013).
8. Leyin A. Improving access to psychological therapies for people with learning disabilities. *Learn Disabil Rev* 2011;**16**:29–37. http://dx.doi.org/10.1108/13595471111185747
9. Lindsay WR. Cognitive therapy. *Psychologist* 1999;**12**:238–41.
10. Hatton C. Psychosocial interventions for adults with intellectual disabilities and mental health problems: A review. *J Ment Health* 2002;**11**:357–74. http://dx.doi.org/10.1080/09638230020023732
11. Willner P, Brace N, Phillips J. Assessment of anger coping skills in individuals with intellectual disabilities. *J Intellect Disabil Res* 2005;**49**:329–39. http://dx.doi.org/10.1111/j.1365-2788.2005.00668.x
12. Taylor JL, Lindsay WR, Willner P. CBT for people with intellectual disabilities: emerging evidence, cognitive ability and IQ effects. *Behav Cognit Psychother* 2008;**36**:723–33. http://dx.doi.org/10.1017/S1352465808004906
13. McCabe MP, McGillivray JA, Newton DC. Effectiveness of treatment programmes for depression among adults with mild/moderate intellectual disability. *J Intellect Disabil Res* 2006;**50**:239–47. http://dx.doi.org/10.1111/j.1365-2788.2005.00772.x
14. McGillivray JA, McCabe MP, Kershaw MM. Depression in people with intellectual disability: an evaluation of a staff-administered treatment program. *Res Dev Disabil* 2008;**29**:524–36. http://dx.doi.org/10.1016/j.ridd.2007.09.005
15. Benson BA, Brooks WT. Aggressive challenging behaviour and intellectual disability. *Curr Opin Psychiatr* 2008;**21**:454–8. http://dx.doi.org/10.1097/YCO.0b013e328306a090
16. Taylor JL, Novaco RW, Gillmer BT, Robertson A, Thorne I. Individual cognitive-behavioural anger treatment for people with mild-borderline intellectual disabilities and histories of aggression: a controlled trial. *Br J Clin Psychol* 2005;**44**:367–82. http://dx.doi.org/10.1348/014466505X29990
17. Rose JL, Dodd L, Rose N. Individual cognitive behavioral intervention for anger. *J Ment Health Res Intellect Disabil* 2008;**1**:97–108. http://dx.doi.org/10.1080/19315860801988368

18. Hughes K, Bellis MA, Jones L, Wood S, Bates G, Eckley L, *et al.* Prevalence and risk of violence against adults with disabilities: a systematic review and meta-analysis of observational studies. *Lancet* 2012;**379**:1621–9. http://dx.doi.org/10.1016/S0140-6736(11)61851-5

19. Allen DG, Lowe K, Moore K, Brophy S. Predictors, costs and characteristics of out of area placement for people with intellectual disability and challenging behaviour. *J Intellect Disabil Res* 2007;**51**:409–16. http://dx.doi.org/10.1111/j.1365-2788.2006.00877.x

20. Emerson E, Robertson J. *Commissioning person centred, cost effective, local support for people with learning difficulties*. London: Social Care Institute for Excellence; 2008.

21. Mental Health Foundation. *Boiling Point*. 2008. URL: www.mentalhealth.org.uk/content/assets/PDF/publications/boiling_point_report.pdf?view=Standard (accessed 5 March 2013).

22. Jenkins R, Rose J, Lovell C. Psychological well-being of staff working with people who have challenging behaviour. *J Intellect Disabil Res* 1997;**41**:502–11. http://dx.doi.org/10.1111/j.1365-2788.1997.tb00743.x

23. Rose J, Jones F, Fletcher B. Investigating the relationship between stress and worker behaviour. *J Intellect Disabil Res* 1998;**42**:163–72. http://dx.doi.org/10.1046/j.1365-2788.1998.00115.x

24. Allen D, Hawkins S, Cooper V. Parents' Use of Physical Interventions in the Management of Their Children's Severe Challenging Behaviour. *J Appl Res Intellect Disabil* 2006;**19**:356–63. http://dx.doi.org/10.1111/j.1468-3148.2006.00292.x

25. Hastings RP. Parental stress and behaviour problems of children with developmental disability. *J Intellect Dev Disabil* 2002;**27**:149–60. http://dx.doi.org/10.1080/1366825021000008657

26. Kiernan C, Alborz A, Mason H, Hester Adrian Research C. *The HARC Challenging Behaviour Project: report 4. Experience and views of parents caring for people with learning disabilities living in the family home*. Manchester: Hester Adrian Research Centre; 1997.

27. Taylor JL, Novaco RW. *Anger treatment for people with developmental disabilities: a theory, evidence and manual-based approach*. Chichester: Wiley; 2005. http://dx.doi.org/10.1002/9780470713631

28. Novaco RW. *Anger control: The development and evaluation of an experimental treatment*. Lexington, MA: Heath; 1975.

29. Novaco RW. Anger. In Kazdin AE, editor. *Encyclopedia of psychology*. Washington, DC: American Psychological Association and Oxford University Press; 2000.

30. Marlatt G, Gordon JR. *Relapse prevention: maintenance strategies in the treatment of addictive behaviors*. New York, NY: Guildford; 1985.

31. Didden R, Duker P, Korzilius H. Meta-analytic study on treatment effectiveness for problem behaviours in individuals who have mental retardation. *Am J Ment Retard* 1997;**101**:387–99.

32. Matson JL, Bamburg JW, Mayville EA, Pinkston J, Bielecki J, Kuhn D, *et al.* Psychopharmacology and mental retardation: a 10 year review (1990–1999). *Res Dev Disabil* 2000;**21**:263–96. http://dx.doi.org/10.1016/S0891-4222(00)00042-1

33. Brosnan J, Healy O. A review of behavioral interventions for the treatment of aggression in individuals with developmental disabilities. *Res Dev Disabil* 2011;**32**:437–46. http://dx.doi.org/10.1016/j.ridd.2010.12.023

34. Jones RM, Arlidge J, Gillham R, Reagu S, van den Bree M, Taylor PJ. Efficacy of mood stabilisers in the treatment of impulsive or repetitive aggression: systematic review and meta-analysis. *Br J Psychiatry* 2011;**198**:93–8. http://dx.doi.org/10.1192/bjp.bp.110.083030

35. Benson BA, Rice CJ, Miranti SV. Effects of anger management training with mentally retarded adults in group treatment. *J Consult Clin Psychol* 1986;**54**:728–9. http://dx.doi.org/10.1037/0022-006X.54.5.728

36. Benson B. *Teaching anger management to persons with mental retardation*. Champaign, IL: International Diagnostic System Inc.; 1992.

37. Benson B. Anger management training: a self control program for people with mild mental retardation. In Bourne N, editor. *Mental health in mental retardation*. Cambridge: Cambridge University Press; 1994. pp. 224–32.

38. Rose J, West C, Clifford D. Group interventions for anger in people with intellectual disabilities. *Res Dev Disabil* 2000;**21**:171–81. http://dx.doi.org/10.1016/S0891-4222(00)00032-9

39. Willner P, Jones J, Tams R, Green G. A randomized controlled trial of the efficacy of a cognitive-behavioural anger management group for clients with learning disabilities. *J Appl Res Intellect Disabil* 2002;**15**:224–35. http://dx.doi.org/10.1046/j.1468-3148.2002.00121.x

40. Lindsay WR, Allan R, Parry C, Macleod F, Cottrell J, Overend H, *et al.* Anger and aggression in people with intellectual disabilities: treatment and follow-up of consecutive referrals and a waiting list comparison. *Clin Psychol Psychother* 2004;**11**:255–64. http://dx.doi.org/10.1002/cpp.415

41. Rose J, Loftus M, Flint B, Carey L. Factors associated with the efficacy of a group intervention for anger in people with intellectual disabilities. *Br J Clin Psychol* 2005;**44**:305–17. http://dx.doi.org/10.1348/014466505X29972

42. Hagiliassis N, Gulbenkoglu H, Di Marco M, Young S, Hudson A. The Anger Management Project: A group intervention for anger in people with physical and multiple disabilities. *J Intellect Dev Disabil* 2005;**30**:86–96. http://dx.doi.org/10.1080/13668250500124950

43. Rose J, O'Brien A, Rose D. Group and individual cognitive behavioural interventions for anger. *Adv Ment Health Learning Disabil* 2009;**3**:45–50.

44. Rose J. Carer reports of the efficacy of cognitive behavioral interventions for anger. *Res Dev Disabil* 2010;**31**:1502–8. http://dx.doi.org/10.1016/j.ridd.2010.06.007

45. Collado-Castillo CJ. *Comparison of a cognitive re-appraisal approach and a problem-solving approach to improve social cognition in adults with intellectual disabilities who exhibit aggressive behavior [3420822]*. New York, NY: Columbia University; 2010.

46. Taylor JL, Novaco RW, Gillmer B, Thorne I. Cognitive-behavioural treatment of anger intensity among offenders with intellectual disabilities. *J Appl Res Intellect Disabil* 2002;**15**:151–65. http://dx.doi.org/10.1046/j.1468-3148.2002.00109.x

47. Taylor JL, Novaco RW, Guinan C, Street N. Development of an imaginal provocation test to evaluate treatment for anger problems in people with intellectual disabilities. *Clin Psychol Psychother* 2004;**11**:233–46. http://dx.doi.org/10.1002/cpp.411

48. Willner P, Tomlinson S. Generalization of anger-coping skills from day-service to residential settings. *J Appl Res Intellect Disabil* 2007;**20**:553–62. http://dx.doi.org/10.1111/j.1468-3148.2007.00366.x

49. Taylor J, Novaco R, Johnson L. Effects of intellectual functioning on cognitive behavioural anger treatment for adults with learning disabilities in secure settings. *Adv Ment Health Learning Disabil* 2009;**3**:51–6.

50. Lecomte T, Leclerc C, Corbière M, Wykes T, Wallace CJ, Spidel A. Group cognitive behavior therapy or social skills training for individuals with a recent onset of psychosis? Results of a randomized controlled trial. *J Nerv Ment Dis* 2008;**196**:866–75. http://dx.doi.org/10.1097/NMD.0b013e31818ee231

51. Willner P. Cognitive behavioural therapy for people with learning disabilities: focus on anger. *Adv Ment Health Learning Disabil* 2007;**1**:14–21.

52. Hassiotis A, Hall I. Behavioural and cognitive-behavioural interventions for outwardly-directed aggressive behaviour in people with learning disabilities. *Cochrane Database Syst Rev* 2008;**3**:CD003406.

53. Curtis NM, Ronan KR, Borduin CM. Multisystemic treatment: a meta-analysis of outcome studies. *J Fam Psychol* 2004;**18**:411–19. http://dx.doi.org/10.1037/0893-3200.18.3.411

54. Henggeler S. Decreasing effect sizes for effectiveness studies-implications for the transport of evidence-based treatments: comment on Curtis, Ronan, and Bourduin. *J Fam Psychol* 2004;**18**:420–3. http://dx.doi.org/10.1037/0893-3200.18.3.420

55. Stevens VJ, Glasgow RE, Hollis JF, Mount K. Implementation and Effectiveness of a Brief Smoking-Cessation Intervention for Hospital Patients. *Mel Care* 2000;**38**:451–9. http://dx.doi.org/10.1097/00005650-200005000-00002

56. Houghton S, Saxon D, Bradburn M, Ricketts T, Hardy G. The effectiveness of routinely delivered cognitive behavioural therapy for obsessive-compulsive disorder: a benchmarking study. *Br J Clin Psychol* 2010;**49**:473–89. http://dx.doi.org/10.1348/014466509X475414

57. Waskow IE. Specification of the technique variable in the NIMH Treatment of Depression Collaborative Research Program. In Williams JBW, Spitzer RL, editors. *Psychotherapy research: where are we, and where should we go?* New York, NY: Guilford; 1984. pp. 150–9.

58. Carroll KM, Rounsaville BJ. Can a technology model be applied to psychotherapy research in cocaine abuse treatment? In Onken LS, Blaine JD, editors. *Psychotherapy and counseling in the treatment of drug abuse (NIDA Research Monograph Series Number 104)*. Rockville, MD: NIDA; 1990. pp. 91–104.

59. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clin Psychol Rev* 1991;**11**:247–66. http://dx.doi.org/10.1016/0272-7358(91)90103-2

60. Santa Ana EJ, Martino S, Ball SA, Nich C, Frankforter TL, Carroll KM. What is usual about 'treatment-as-usual'? Data from two multisite effectiveness trials. *J Subst Abuse Treat* 2008;**35**:369–79. http://dx.doi.org/10.1016/j.jsat.2008.01.003

61. Waller G, Stringer H, Meyer C. What cognitive behavioural techniques do therapists report using when delivering cognitive behavioural therapy for the eating disorders? *J Consult Clin Psychol* 2012;**80**:171–5. http://dx.doi.org/10.1037/a0026559

62. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, *et al.* Treatment Fidelity Workgroup of the NIH Behavior Change Consortium. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004;**23**:443–51. http://dx.doi.org/10.1037/0278-6133.23.5.443

63. Eames C, Daley D, Hutchings J, Whitaker CJ, Jones K, Hughes JC, *et al.* Treatment fidelity as a predictor of behaviour change in parents attending group-based parent training. *Child Care Health Dev* 2009;**35**:603–12. http://dx.doi.org/10.1111/j.1365-2214.2009.00975.x

64. Saini M. A meta-analysis of the psychological treatment of anger: developing guidelines for evidence-based practice. *J Am Acad Psychiatr Law* 2009;**37**:473–88.

65. Young J, Beck AT. *Cognitive Therapy Scale Rating Manual*. Philadelphia, PA: University of Pennsylvania Psychotherapy Research Unit; 1980.

66. Haddock G, Devane S, Bradshaw T, McGovern J, Tarrier N, Kinderman P, *et al.* An investigation into the psychometric properties of the cognitive therapy scale for psychosis (CTS-Psy). *Behav Cognit Psychother* 2001;**29**:221–33. http://dx.doi.org/10.1017/S1352465801002089

67. Jahoda A, Selkirk M, Trower P, Pert C, Kroese BS, Dagnan D, *et al.* The balance of power in therapeutic interactions with individuals who have intellectual disabilities. *Br J Clin Psychol* 2009;**48**:63–77. http://dx.doi.org/10.1348/014466508X360746

68. Kolakowski L. An overall view of positivism. In Hammersley M, editor. *Social research, philosophy, politics and practice*. London: Sage; 1993.

69. Smith JA, Flowers P, Larkin M. *Interpretative phenomenological analysis: theory method and research*. London: Sage; 2009.

70. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. http://dx.doi.org/10.1191/1478088706qp063oa

71. Blackwood B, O'Halloran P, Porter S. On the problems of mixing RCTs with qualitative research: the case of the MRC framework for the evaluation of complex healthcare interventions. *J Res Nurs* 2010;**15**:511–21. http://dx.doi.org/10.1177/1744987110373860

72. Prowse M. *Background note. Aid effectiveness: the role of qualitative research in impact evaluation*. London: Overseas Development Institute; 2007.

73. McLeod J. *Qualitative research in counselling and psychotherapy*. 2nd edn. London: Sage; 2011.

74. Willner P, Jahoda A, Rose J, Stenfert-Kroese B, Hood K, Townson J, *et al.* Anger management for people with mild to moderate learning disabilities: study protocol for a multi–centre cluster randomised controlled trial of a manualised intervention delivered by day-service staff. *Trials* 2011;**12**:36. http://dx.doi.org/10.1186/1745-6215-12-36

75. Scott NW, McPherson GC, Ramsay CR, Campbell MK. The method of minimization for allocation to clinical trials: a review. *Control Clin Trials* 2002;**23**:662–74. http://dx.doi.org/10.1016/S0197-2456(02)00242-8

76. Douglas GA, Bland JM. Treatment allocation by minimisation. *BMJ* 2005;**330**:843. http://dx.doi.org/10.1136/bmj.330.7495.843

77. Cummins RA. *The Comprehensive Quality of Life Scale: Intellectual Disability*. 5th edn. Melbourne: Deakin University; 1997.

78. Wechsler D. *The Wechsler abbreviated scale of intelligence*. San Antonio, TX: The Psychological Corporation; 1999.

79. Dunn LM, Sewell J, Styles B (editor). *British picture vocabulary scale (BPVS-III)*. 3rd edn. Windsor : NFER-Nelson; 2009.

80. Hatton C, Emerson E, Robertson J, Gregory N, Kessissoglou S, Perry J, *et al.* The adaptive behavior scale-residential and community (part I): towards the development of a short form. *Res Dev Disabil* 2001;**22**:273–88. http://dx.doi.org/10.1016/S0891-4222(01)00072-5

81. Novaco RW. Anger as a risk factor for violence among the mentally disordered. In Monahan J, Streadman HJ, editor. *Violence and disorder: developments in risk assessment*. Chicago, IL: University of Chicago Press; 1994. pp. 21–59.

82. Mindham J, Espie CA. Glasgow Anxiety Scale for people with an Intellectual Disability (GAS-ID): development and psychometric properties of a new measure for use with people with mild intellectual disability. *J Intellect Disabil Res* 2003;**47**:22–30. http://dx.doi.org/10.1046/j.1365-2788.2003.00457.x

83. Cuthill FM, Espie CA, Cooper S-A. Development and psychometric properties of the Glasgow Depression Scale for people with a learning disability. *Br J Psychiatr* 2003;**182**:347–53. http://dx.doi.org/10.1192/bjp.182.4.347

84. Dagnan D, Sandhu S. Social comparison, self-esteem and depression in people with intellectual disability. *J Intellect Disabil Res* 1999;**43**:372–9. http://dx.doi.org/10.1046/j.1365-2788.1999.043005372.x

85. Aman MG, Singh NN, Stewart AW, Field CJ. The aberrant behavior checklist: a behavior rating scale for the assessment of treatment effects. *Am J Ment Defic* 1985;**89**:485–91.

86. Oliver PC, Crawford MJ, Rao B, Reece B, Tyrer P. Modified Overt Aggression Scale (MOAS) for people with intellectual disability and aggressive challenging behaviour: a reliability study. *J Appl Res Intellect Disabil* 2007;**20**:368–72. 86. http://dx.doi.org/10.1111/j.1468-3148.2006.00346.x

87. Robertson J, Emerson E, Pinkney L, Caesar E, Felce D, Meek A, *et al.* Quality and costs of community-based residential supports for people with mental retardation and challenging behavior. *Am J Ment Retard* 2004;**109**:332–44. http://dx.doi.org/10.1352/0895-8017(2004)109<332:QACOCR>2.0.CO;2

88. Dagnan D, Grant F, McDonnell A. Understanding challenging behaviour in older people: The development of the controllability beliefs scale. *Behav Cognit Psychother* 2004;**32**:501–6. http://dx.doi.org/10.1017/S1352465804001675

89. O'Brien A. *How might people with intellectual disabilities be supported to age 'successfully'?* ClinPsyD thesis. Birmingham: University of Birmingham; 2002

90. Aman MG, Singh NN. *Aberrant behavior checklist manual*. New York, NY: Slosson Educational Publications; 1986.

91. Dagnan D, Hull A, McDonnell, A. The Controllability Beliefs Scale used with carers of people with intellectual disabilities: psychometric properties [published online ahead of print 4 April 2012]. *J Intellect Disabil Res* 2013; in press. http://dx.doi.org/10.1111/j.1365-2788.2012.01554.x

92. Elliott R, Fischer CT, Rennie DL. Evolving guidelines for publication of qualitative research studies in psychology and related fields. *Br J Clin Psychol* 1999;**38**:215–29. http://dx.doi.org/10.1348/014466599162782

93. Beecham J. Costing psychiatric interventions. In Thornicroft GJ, Brewin CR, Wing JK, editors. *Measuring mental health needs*. London: Gaskell; 1992.

94. Beecham J. Collecting and estimating costs. In Knapp MRJ, editor. *The economic evaluation of mental health care*. Aldershot: Arena; 1995.

95. Emerson E, Robertson J, Gregory N, Kessissoglou S, Hatton C, Hallam A, *et al.* The quality and costs of community-based residential supports and residential campuses for people with severe and complex disabilities. *J Intellect Dev Disabil* 2000;**25**:263–79. http://dx.doi.org/10.1080/13668250020019575

96. Felce D, Perry J, Romeo R, Robertson J, Meek A, Emerson E, *et al.* Outcomes and costs of community living: semi-independent living and fully staffed group homes. *Am J Ment Retard* 2008;**113**:87–101. http://dx.doi.org/10.1352/0895-8017(2008)113[87:OACOCL]2.0.CO;2

97. Quade D. *Rank analysis of covariance*. *J Am Stat Assoc* 1967;**62**:1187–200. http://dx.doi.org/10.1080/01621459.1967.10500925

98. Hewitt CE, Torgerson DJ, Miles JNV. Is there another way to take account of noncompliance in randomized controlled trials? *Can Med Assoc J* 2006;**175**:347. http://dx.doi.org/10.1503/cmaj.051625

99. Dunn G, Maracy M, Dowrick C, Ayuso-Mateos JL, Dalgard OS, Page H, *et al.* Estimating psychological treatment effects from a randomised controlled trial with both non-compliance and loss to follow-up. *Br J Psychiatry* 2003;**183**:323–31. http://dx.doi.org/10.1192/bjp.183.4.323

100. Jo B, Asparouhov T, Muthén BO. Intention-to-treat analysis in cluster randomized trials with noncompliance. *Stat Med* 2008;**27**:5565–77. http://dx.doi.org/10.1002/sim.3370

101. Shrout PE, Fleiss, JL. Intraclass correlations: uses in assessing rater reliability. *Psychol Bull* 1979;**86**:420–8. http://dx.doi.org/10.1037/0033-2909.86.2.420

102. Smith JA. Beyond the divide between cognition and discourse: using interpretative phenomenological analysis in health psychology. *Psychol Health* 1996;**11**:261–71. http://dx.doi.org/10.1080/08870449608400256

103. Yardley L. Demonstrating validity in qualitative psychology. In Smith JA, editor. *Qualitative psychology: a practical guide to methods*. 2nd edn. London: Sage; 2008.

104. Aronson J. A pragmatic view of thematic analysis. *Qual Rep* 1994;**2**:131–4.

105. Curtis L, editor. *Unit costs of health and social care 2010*. Canterbury: PSSRU, University of Kent; 2010.

106. Efron B, Tibshirani, R. *An introduction to the bootstrap*. New York, NY: Chapman and Hall; 1993.

107. Roberts C, Torgerson D. Baseline imbalance in randomised controlled trials. *BMJ* 1999;**319**:185. http://dx.doi.org/10.1136/bmj.319.7203.185

108. Eaton LF, Menolascino FJ. Psychiatric disorders in the mentally retarded: types, problems and challenges. *Am J Psychiatr* 1982;**139**:1297–303.

109. Borthwick-Duffy SA. Epidemiology and prevalence of psychopathology in people with mental retardation. *J Consult Clin Psychol* 1994;**62**:17–27. http://dx.doi.org/10.1037/0022-006X.62.1.17

110. Deb S, Thomas M, Bright C. Mental disorder in adults with intellectual disability. 1: Prevalence of functional psychiatric illness among a community-based population aged between 16 and 64 years. *J Intellect Disabil Res* 2001;**45**:495–505. http://dx.doi.org/10.1046/j.1365-2788.2001.00374.x

111. Moss S, Emerson E, Kiernan C, Turner S, Hatton C, Alborz A. Psychiatric symptoms in adults with learning disability and challenging behaviour. *Br J Psychiatry* 2000;**177**:452–6. http://dx.doi.org/10.1192/bjp.177.5.452

112. Hull L, Farrin L, Unwin C, Everitt B, Wykes T, David AS. Anger, psychopathology and cognitive inhibition: a study of UK servicemen. *Pers Ind Diff* 2003;**35**:1211–26. http://dx.doi.org/10.1016/S0191-8869(02)00329-X

113. Novaco RW. Anger and psychopathology. In Potegal M, Stemmler G, Spielberger C, editors. *International handbook of anger*. New York, NY: Springer; 2010. pp. 465–97. http://dx.doi.org/10.1007/978-0-387-89676-2_27

114. Ghazinour M, Richter J. Anger related to psychopathology, temperament, and character in healthy individuals an explorative study. *Soc Behav Pers* 2009;**37**:1197–212. http://dx.doi.org/10.2224/sbp.2009.37.9.1197

115. Tyrer P, Oliver-Africano P, Romeo R, Knapp M, Dickens S, Bouras N, *et al.* Neuroleptics in the treatment of aggressive challenging behaviour for people with intellectual disabilities: a randomised controlled trial (NACHBID). *Health Technol Assess* 2009;**13**(21).

116. Rose JL, Gerson DF. Assessing anger in people with intellectual disability. *J Intellect Dev Disabil* 2009;**34**:116–22. http://dx.doi.org/10.1080/13668250902845194

117. Felce D, Kerr M, Hastings RP. A general practice-based study of the relationship between indicators of mental illness and challenging behaviour among adults with intellectual disabilities. *J Intellect Disabil Res* 2009;**53**:243–54. http://dx.doi.org/10.1111/j.1365-2788.2008.01131.x

118. Felce D, Perry J, Lowe K, Jones E. The Impact of Autism or Severe Challenging Behaviour on Lifestyle Outcome in Community Housing. *J Appl Res Intellect Disabil* 2011;**24**:95–104. http://dx.doi.org/10.1111/j.1468-3148.2010.00571.x

119. Borthwick-Duffy SA. Prevalence of destructive behaviours. destructive behaviour in developmental disabilities: diagnosis and treatment. Thousand Oaks, CA: Sage; 1994. pp. 3–23.

120. Holden B, Gitlesen JP. A total population study of challenging behaviour in the county of Hedmark, Norway: prevalence, and risk markers. *Res Dev Disabil* 2006;**27**:456–65. http://dx.doi.org/10.1016/j.ridd.2005.06.001

121. McConatha JT, Leone FM, Armstrong JM. Emotional control in adulthood. *Psychol Rep* 1997;**80**:499–507. http://dx.doi.org/10.2466/pr0.1997.80.2.499

122. Gross JJ, Carstensen LL, Pasupathi M, Tsai J, Götestam Skorpen C, Hsu AYC. Emotion and aging: experience, expression, and control. *Psychol Aging* 1997;**12**:590–9. http://dx.doi.org/10.1037/0882-7974.12.4.590

123. Phillips LH, Henry JD, Hosie JA, Milne AB. Age, anger regulation and well-being. *Aging Ment Health* 2006;**10**:250–6. http://dx.doi.org/10.1080/13607860500310385

124. Tangney JP, Hill-Barlow D, Wagner PE, Marschall DE, Borenstein JK, Sanftner J, *et al.* Assessing individual differences in constructive versus destructive responses to anger across the lifespan. *J Pers Soc Psychol* 1996;**70**:780–96. http://dx.doi.org/10.1037/0022-3514.70.4.780

125. Thomas SP. Women's anger: causes, manifestations, and correlates. In Spielberger. CD, Sarason IG, editors. *Stress and emotion: anxiety, anger, and curiosity*. Washington, DC: Taylor & Francis; 1995. pp. 53–74.

126. Thomas SP. Age Differences in anger frequency, intensity, and expression. *J Am Psychiatr Nurses Assoc* 2002;**8**:44–50. http://dx.doi.org/10.1067/mpn.2002.124412

127. Riediger M, Voelkle MC, Ebner NC, Lindenberger U. Beyond 'happy, angry, or sad?': Age-of-poser and age-of-rater effects on multi-dimensional emotion perception. *Cognit Emot* 2011;**25**:968–82. http://dx.doi.org/10.1080/02699931.2010.540812

128. Crocker AG, Mercier C, Lachapelle Y, Brunet A, Morin D, Roy ME. Prevalence and types of aggressive behaviour among adults with intellectual disabilities. *J Intellect Disabil Res* 2006;**50**:652–61. http://dx.doi.org/10.1111/j.1365-2788.2006.00815.x

129. Tyrer F, McGrother CW, Thorp CF, Donaldson M, Bhaumik S, Watson JM, *et al.* Physical aggression towards others in adults with learning disabilities: prevalence and associated factors. *J Intellect Disabil Res* 2006;**50**:295–304. http://dx.doi.org/10.1111/j.1365-2788.2005.00774.x

130. McClintock K, Hall S, Oliver C. Risk markers associated with challenging behaviours in people with intellectual disabilities: a meta-analytic study. *J Intellect Disabil Res* 2003;**47**:405–16. http://dx.doi.org/10.1046/j.1365-2788.2003.00517.x

131. Lowe K, Allen D, Jones E, Brophy S, Moore K, James W. Challenging behaviours: prevalence and topographies. *J Intellect Disabil Res* 2007;**51**:625–36. http://dx.doi.org/10.1111/j.1365-2788.2006.00948.x

132. Felce D, Kerr M. Investigating low adaptive behaviour and presence of the triad of impairments characteristic of autistic spectrum disorder as indicators of risk for challenging behaviour among adults with intellectual disabilities. *J Intellect Disabil Res* 2013;**57**:128–38. http://dx.doi.org/10.1111/j.1365-2788.2011.01524.x

133. Tynan H, Allen D. The Impact of Service User Cognitive Level on Carer Attributions for Aggressive Behaviour. *J Appl Res Intellect Disabil* 2002;**15**:213–23. http://dx.doi.org/10.1046/j.1468-3148.2002.00120.x

134. Mills S, Rose J. The relationship between challenging behaviour, burnout and cognitive variables in staff working with people who have intellectual disabilities. *J Intellect Disabil Res* 2011;**55**:844–57. http://dx.doi.org/10.1111/j.1365-2788.2011.01438.x

135. MacKinlay L, Langdon PE. Staff attributions towards men with intellectual disability who have a history of sexual offending and challenging behaviour. *J Intellect Disabil Res* 2009;**53**:807–15. http://dx.doi.org/10.1111/j.1365-2788.2009.01194.x

136. Dilworth JA, Phillips N, Rose J. Factors Relating to Staff Attributions of Control Over Challenging Behaviour. *J Appl Res Intellect Disabil* 2011;**24**:29–38. http://dx.doi.org/10.1111/j.1468-3148.2010.00570.x

137. Stenfert Kroese B, Jahoda A, Pert C, Trower P, Dagnan D, Selkirk M. Carers' Expectations and Views of Cognitive Behaviour Therapy for Adults with Intellectual Disabilities. *J Appl Res Intellect Disabil* 2013; in press.

138. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;**33**:159–74. http://dx.doi.org/10.2307/2529310

139. Luborsky L, Rosenthal R, Diguer L, Andrusyna TP, Berman JS, Levitt JT, *et al.* The dodo bird verdict is alive and well – mostly. *Clin Psychol Sci Pract* 2002;**9**:2–12. http://dx.doi.org/10.1093/clipsy/9.1.2

140. Messer SB, Wampold BE. Let's face facts: common factors are more potent than specific therapy ingredients. *Clin Psychol Sci Pract* 2002;**9**:21–5. http://dx.doi.org/10.1093/clipsy.9.1.21

141. Horvath AO, Bedi RP. The alliance. In Norcross J, editor. *Psychotherapy relationships that work: therapist contributions and responsiveness to patients*. London: Oxford University Press; 2002.

142. Cahill J, Barkham M, Hardy G, Gilbody S, Richards D, Bower P, *et al.* A review and critical appraisal of measures of therapist–patient interactions in mental health settings. *Health Technol Assess* 2008;**12**(24).

143. Willner P. Readiness for cognitive therapy in people with intellectual disabilities. *J Appl Res Intellect Disabil* 2006;**19**:5–16. http://dx.doi.org/10.1111/j.1468-3148.2005.00280.x

144. Strupp HH, Hadley SW. Specific vs nonspecific factors in psychotherapy: a controlled study of outcome. *Arch Gen Psychiatr* 1979;**36**:1125–36. http://dx.doi.org/10.1001/archpsyc.1979.01780100095009

145. Westbrook D, Sedgwick-Taylor A, Bennett-Levy J, Butler G, McManus F. A pilot evaluation of a brief CBT training course: impact on trainees' satisfaction, clinical skills and patient outcomes. *Behav Cognit Psychother* 2008;**36**:569–79. http://dx.doi.org/10.1017/S1352465808004608

146. Oliver PC, Piachaud J, Done J, Regan A, Cooray S, Tyrer P. Difficulties in conducting a randomized controlled trial of health service interventions in intellectual disability: implications for evidence-based practice. *J Intellect Disabil Res* 2002;**46**:340–5. http://dx.doi.org/10.1046/j.1365-2788.2002.00408.x

147. Pawson R, Tilley N. *Realistic evaluation*. London: Sage; 1997.

148. DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. *Arch Intern Med* 2000;**160**:2101–7. http://dx.doi.org/10.1001/archinte.160.14.2101

149. Daughters SB, Lejuez CW, Bornovalova MA, Kahler CW, Strong DR, Brown RA. Distress tolerance as a predictor of early treatment dropout in a residential substance abuse treatment facility. *J Abnorm Psychol* 2005;**114**:729–34. http://dx.doi.org/10.1037/0021-843X.114.4.729

150. Berkman ND, Lohr KN, Bulik CM. Outcomes of eating disorders: a systematic review of the literature. *Int J Eat Disord* 2007;**40**:293–309. http://dx.doi.org/10.1002/eat.20369

151. Bradbury KE, Clarke I. Cognitive behavioural therapy for anger management: effectiveness in adult mental health services. *Behav Cognit Psychother* 2007;**35**:201–8. http://dx.doi.org/10.1017/S135246580600333X

152. Howard KI, Kopta SM, Krause MS, Orlinsky DE. The dose–effect relationship in psychotherapy. *Am Psychol* 1986;**41**:159–64. http://dx.doi.org/10.1037/0003-066X.41.2.159

153. Hansen NB, Lambert MJ, Forman EM. The Psychotherapy Dose-Response Effect and Its Implications for Treatment Delivery Services. *Clin Psychol Sci Pract* 2002;**9**:329–43. http://dx.doi.org/10.1093/clipsy.9.3.329

154. Lindsay WR, Jahoda A, Willner P. Adapting psychological therapies for people with intellectual disabilities II: Treatment approaches and modifications. In Taylor JL, Lindsay, WR, Hastings RP, Hatton C, editors. *Psychological therapies for adults with intellectual disabilities*. Chichester: Wiley-Blackwell. pp.85–100.

155. Preacher K, Hayes A. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. *Behav Res Meth* 2008;**40**:879–91. http://dx.doi.org/10.3758/BRM.40.3.879

156. Bender M. The unoffered chair: the history of therapeutic disdain towards people with learning disability. *Clin Psychol Forum* 1993;**54**:7–12.

157. Jones J, Minnes P, Elms J, Paret L, Vilela T. Anger management group for persons with dual diagnosis: a pilot study. *J Dev Disabil* 2007;**13**:37–46.

158. Chambless DL, Hollon SD. Defining empirically supported therapies. *J Consult Clin Psychol* 1998;**66**:7–18. http://dx.doi.org/10.1037/0022-006X.66.1.7

159. Luborsky L, Diguer L, Luborsky E, Singer B, Dickter D, Schmidt KA. The efficacy of dynamic psychotherapies: is it true that ‘everyone has won and all must have prizes?’. In Miller NE, Luborsky L, Barber JP, Docherty JP, editors. *Psychodynamic treatment research: a handbook for clinical practice*. New York, NY: Basic Books; 1993. pp. 497–516.

160. Jahoda A, Pert C, Squire J, Trower P. Facing stress and conflict: a comparison of the predicted responses and self-concepts of aggressive and non-aggressive people with intellectual disability. *J Intellect Disabil Res* 1998;**42**:360–9. http://dx.doi.org/10.1046/j.1365-2788.1998.00143.x

161. Kroese BS, Gillott A, Atkinson V. Consumers with Intellectual Disabilities as Service Evaluators. *J Appl Res Intellect Disabil* 1998;**11**:116–28. http://dx.doi.org/10.1111/j.1468-3148.1998.tb00054.x

162. Atkinson D. Research interviews with people with mental handicaps. *Ment Handicap Res* 1988;**1**:75–90. http://dx.doi.org/10.1111/j.1468-3148.1988.tb00006.x

163. Sigelman CK, Budd EC, Spanhel CL, Schoenrock CJ. When in doubt, say yes: acquiescence in interviews with mentally retarded persons. *Ment Retard* 1981;**19**:53–8.

164. Perry J, Felce D. Subjective and objective quality of life assessment: responsiveness, response bias, and resident: proxy concordance. *Ment Retard* 2002;**40**:445–56. http://dx.doi.org/10.1352/0047-6765(2002)040<0445:SAOQOL>2.0.CO;2

165. Beck AT, Rush AJ, Shaw BF, Emery G. *Cognitive therapy of depression*. New York, NY: Guildford; 1979.

166. Novaco RW. The cognitive regulation of anger and stress. In Kendall P, Hollon, C, editors. *Cognitive-behavioural interventions: theory research and procedures*. New York, NY: Academic Press; 1979.

167. British Psychological Society (BPS). *Psychological interventions for severely challenging behaviours shown by people with learning disabilities*. Leicester: BPS; 2005.

168. Royal College of Psychiatrists (RCP), British Psychological Society (BPS) and Royal College of Speech and Language Therapists (RCSLT). *Challenging behaviour: a unified approach*. Leicester: BPS; 2007.

169. Rose J, West C. Assessment of anger in people with intellectual disabilities. *J Appl Res Intellect Disabil* 1999;**12**:211–24. http://dx.doi.org/10.1111/j.1468-3148.1999.tb00078.x

170. Hayes SC, Zettle RD, Rosenfarb I. Rule following. In Hayes SC, editor. *Rule-governed behavior: cognition, contingencies, and instructional control*. New York, NY: Plenum Press; 1989. pp. xix and 391.

171. Department of Health (DoH). *Valuing people: a new strategy for learning disability for the 21st century*. London: DoH; 2001.

172. Department of Health (DoH). *Services for people with learning disabilities and challenging behaviour or mental health needs*. Revised edn. London: DoH; 2007.

173. Sandhu DK, Rose J. How do therapists contribute to therapeutic change in sex offender treatment: an integration of the literature. *J Sex Aggression* 2011:1–15.

174. Gilbert P, Miles JNV. Sensitivity to social put-down: its relationship to perceptions of social rank, shame, social anxiety, depression, anger and self-other blame. *Pers Indiv Differ* 2000;**29**:757–74. http://dx.doi.org/10.1016/S0191-8869(99)00230-5

175. Schalast N, Redies M, Collins M, Stacey J, Howells K. EssenCES, a short questionnaire for assessing the social climate of forensic psychiatric wards. *Crim Behav Ment Health* 2008;**18**:49–58. http://dx.doi.org/10.1002/cbm.677

176. Thompson L, Rose J. Does organizational climate impact upon burnout in staff who work with people with intellectual disabilities? A systematic review of the literature. *J Intellectual Disabil* 2011;**15**:177–93. http://dx.doi.org/10.1177/1744629511419616

177. Davis JP, Judd FK, Herrman H. Depression in adults with intellectual disability. Part 1: A Review. *Aust N Z J Psychiatry* 1997;**31**:232–42. http://dx.doi.org/10.3109/00048679709073826

178. McBrien JA. Assessment and diagnosis of depression in people with intellectual disability. *J Intellect Disabil Res* 2003;**47**:1–13. http://dx.doi.org/10.1046/j.1365-2788.2003.00455.x

179. Stenfert Kroese B, Rose J. *Mental health services for adults with learning disabilities*. London: Judith Trust; 2011.

180. Rose N, Rose J, Kent S. Staff training in intellectual disability services: a review of the literature and implications for mental health services provided to individuals with intellectual disability. *Int J Dev Disabil* 2012;**58**:24–39.

181. Repp AC, Felce D, de Kock U. Observational studies of staff working with mentally retarded persons: a review. *Res Dev Disabil* 1987;**8**:331–50. http://dx.doi.org/10.1016/0891-4222(87)90011-4

182. Felce D, Saxby H, de Kock U, Repp AC, Ager A, Blunden R. To what behaviors do attending adults respond? A replication. *Am J Ment Defic* 1987;**91**:496–504.

183. Felce D, Lowe K, Jones E. Staff activity in supported housing services. *J Appl Res Intellect Disabil* 2002;**15**:388–403. http://dx.doi.org/10.1046/j.1468-3148.2002.00130.x

184. Cattermole M, Jahoda A, Markova I. Quality of Life for People with Learning Difficulties Moving to Community Homes. *Disabil Handicap Soc* 1990;**5**:137–52. http://dx.doi.org/10.1080/02674649066780141

185. Booth T, Booth W. The use of depth interviewing with vulnerable subjects: lessons from a research study of parents with learning difficulties. *Soc Sci Med* 1994;**39**:415–24. http://dx.doi.org/10.1016/0277-9536(94)90139-2

186. Hoole L, Morgan S. 'It's only right that we get involved': service-user perspectives on involvement in learning disability services. *Br J Learn Disabil* 2011;**39**:5–10.

187. Cookson A, Dickson JM. The subjective experiences of people with an intellectual disability and diagnosis of schizophrenia who are detained in a medium secure unit. *J Appl Res Intellect Disabil* 2010;**23**:379–89. http://dx.doi.org/10.1111/j.1468-3148.2010.00554.x

188. Donner B, Mutter R, Scior K. Mainstream in-patient mental health care for people with intellectual disabilities: service user, carer and provider experiences. *J Appl Res Intellect Disabil* 2010;**23**:214–25. http://dx.doi.org/10.1111/j.1468-3148.2009.00527.x

189. Merriman C, Beail N. Service user views of long-term individual psychodynamic psychotherapy. *Adv Ment Health Learning Disabil* 2009;**3**:42–7.

190. Pert C, Jahoda A, Stenfert Kroese B, Trower P, Dagnan D, Selkirk M. Cognitive behavioural therapy from the perspective of clients with mild intellectual disabilities: a qualitative investigation of process issues [published online ahead of print 25 April 2012]. *J Intellect Disabil Res* 2013; in press. http://dx.doi.org/10.1111/j.1365-2788.2012.01546.x.

191. MacDonald J, Sinason V, Hollins S. An interview study of people with learning disabilities' experience of, and satisfaction with, group analytic therapy. *Psychol Psychother Theor Res Pract* 2003;**76**:433–53. http://dx.doi.org/10.1348/147608303770584764

192. Bazeley P. The bricoleur with a computer: piecing together qualitative and quantitative data. *Qual Health Res* 1999;**9**:279–87. http://dx.doi.org/10.1177/104973299129121749

193. Cresswell JW. *Research design: qualitative and quantitative approaches*. Thousand Oaks, CA: Sage; 2003.

194. Tashakkori A, Teddlie C, editors. *Handbook of mixed methods in social and behavioral research*. Thousand Oaks, CA: Sage; 2003.

195. Stenfert Kroese B, Gillot A, Atkinson V. Consumers with intellectual disabilities as service evaluators. *J Appl Res Intellect Disabil* 1998;**11**:116–28. http://dx.doi.org/10.1111/j.1468-3148.1998.tb00054.x

196. Finlay WM, Lyons E. Acquiescence in people who have mental retardation. *Ment Retard* 2002;**40**:14–29. http://dx.doi.org/10.1352/0047-6765(2002)040<0014:AIIWPW>2.0.CO;2

197. Bohart AC, Greenberg LS. *Empathy: where are we and where do we go from here? Empathy reconsidered: new directions in psychotherapy*. Washington, DC: American Psychological Association; 1997. pp. 419–49. http://dx.doi.org/10.1037/10226-031

198. Orlinsky DE, Ronnestad MH, Willutzki U. Fifty years of Psychotherapy process outcome research: continuity and change. In Lambert MJ, editor. *Bergin and Garfield's handbook of psychotherapy and behavioral change*. New York, NY: Wiley; 2003. pp. 307–90.

199. Emerson E, Malam S, Davies I, Spencer K. *Adults with learning difficulties in England 2003/2004*. London: NHS Health and Social Care Information Centre; 2005.

200. Forrester-Jones R, Carpenter J, Coolen-Schrijner P, Cambridge P, Tate A, Beecham J, *et al.* The social networks of people with intellectual disability living in the community 12 years after resettlement from long-stay hospitals. *J Appl Res Intellect Disabil* 2006;**19**:285–95. http://dx.doi.org/10.1111/j.1468-3148.2006.00263.x

201. Gilbert P, Leahy RL. *The therapeutic relationship in the cognitive behavioral psychotherapies*. Hove: Routledge; 2007.

202. Onyett S. *New ways of working for applied psychologists in health and social care: Working psychologically in teams*. Leicester: British Psychological Society; 2007.

203. Hall JA. Psychological-mindedness: a conceptual model. *Am J Psychother* 1992;**46**:131–40.

204. Shill MA, Lumley MA. The psychological mindedness scale: factor structure, convergent validity and gender in a non-psychiatric sample. *Psychol Psychother Theor Res Pract* 2002;**75**:131–50. http://dx.doi.org/10.1348/147608302169607

205. Rose J, Harris P, Burns M. Supporting yourself and your team. In Hardy S, Joyce T, editors. *Challenging Behaviour*. Brighton: Pavilion; 2011.

206. Cartwright D, Zanden A. *Group dynamics. research and theory*. 3rd edn. New York, NY: Harper Row; 1968.

207. Bloch S, Crouch E, Reibstein J. Therapeutic factors in group psychotherapy: a review. *Arch Gen Psychiatr* 1981;**38**:519–26. http://dx.doi.org/10.1001/archpsyc.1980.01780300031003

208. Scott C, Tacchi MJ, Jones R, Scott J. Acute and one-year outcome of a randomised controlled trial of brief cognitive therapy for major depressive disorder in primary care. *Br J Psychiatry* 1997;**171**:131–4. http://dx.doi.org/10.1192/bjp.171.2.131

209. Cuijpers P. Bibliotherapy in unipolar depression: a meta-analysis. *J Behav Ther Exp Psychiatr* 1997;**28**:139–47. http://dx.doi.org/10.1016/S0005-7916(97)00005-0

210. Proudfoot J, Ryden C, Everitt B, Shapiro DA, Goldberg D, Mann A, *et al.* Clinical efficacy of computerised cognitive–behavioural therapy for anxiety and depression in primary care: randomised controlled trial. *Br J Psychiatry* 2004;**185**:46–54. http://dx.doi.org/10.1192/bjp.185.1.46

211. Bower P, Gilbody S. Stepped care in psychological therapies: access, effectiveness and efficiency. *Br J Psychiatry* 2005;**186**:11–17. http://dx.doi.org/10.1192/bjp.186.1.11

212. Knapp M, Romeo R, Beecham J. *The economic consequences of autism in the UK*. London: Foundation for People with Learning Disabilities; 2007.

213. Hospital and Community Health Service (HCHS) Pay & Price Series. *Hospital and community health services pay and price inflation*. URL: www.doh.gov.uk/doh/finman.nsf/af3d43e36a4c8f8500256722005b77f8/3cb518015eeced2f8025780100320e43?OpenDocument] (accessed 26 October 2011).

214. Knapp M, Comas-Herrera A, Astin J, Beecham J, Pendaries C. Intellectual disability, challenging behaviour and cost in care accommodation: what are the links? *Health Soc Care Community* 2005;**13**:297–306. http://dx.doi.org/10.1111/j.1365-2524.2005.00539.x

215. Curtis L. *Unit costs of health and social care 2007*. Canterbury: PSSRU, University of Kent; 2007.

216. Curtis L. *Unit costs of health and social care 2009*. Canterbury: PSSRU, University of Kent; 2009.

217. Review Body on Doctors’ and Dentists’ Remuneration. Thirty-Ninth Report 2010. Cm 7837. Norwich: The Stationery Office; 2010.

218. Department of Health. *The General Ophthalmic Services Contracts (Payments) Directions*. 2010. URL: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_114692 (accessed 22 April 10).

219. Heslin M, McCrone P, Flach C, Fearon P, Morgan K, Jones P, *et al.* The economic cost of pathways to care in first episode psychosis. *Int Rev Psychiatr* 2011;**23**:55–60. http://dx.doi.org/10.3109/09540261.2010.544644

220. Curtis L. *Unit costs of health and social care 2005*. Canterbury: PSSRU, University of Kent; 2005.

221. Local Government Association. *Local Government Earnings Survey 2010–11*. URL: www.local.gov.uk/web/guest/local-government-intelligence/-/journal_content/56/10171/3015313/ARTICLE-TEMPLATE (accessed 5 January 2012).

222. National Joint Council (NJC) for Local Government Services. *National Agreement on Pay and Conditions of Service (updated June 2005).* 'Green Book'. URL: www.atl.org.uk/Images/Green%20book.pdf (accessed 5 March 2013).

223. National Association of Adult Placement Services (NAAPS). *A business case for shared lives*. Liverpool: NAAPS; 2009.

Appendix 1 Protocol

Willner *et al. Trials* 2011, **12**:36
http://www.trialsjournal.com/content/12/1/36

TRIALS

STUDY PROTOCOL **Open Access**

Anger management for people with mild to moderate learning disabilities: Study protocol for a multi-centre cluster randomized controlled trial of a manualized intervention delivered by day-service staff

Paul Willner[1*], Andrew Jahoda[2], John Rose[3], Biza Stenfert-Kroese[3], Kerenza Hood[4], Julia K Townson[4], Jacqueline Nuttall[4], David Gillespie[4], David Felce[5]

Abstract

Background: Cognitive behaviour therapy (CBT) is the treatment of choice for common mental health problems, but this approach has only recently been adapted for people with learning disabilities, and there is a limited evidence base for the use of CBT with this client group. Anger treatment is the one area where there exists a reasonable number of small controlled trials. This study will evaluate the effectiveness of a manualized 12-week CBT intervention for anger. The intervention will be delivered by staff working in the day services that the participants attend, following training to act as 'lay therapists' by a Clinical Psychologist, who will also provide supervision.

Methods/Design: This is a multi-centre cluster randomized controlled trial of a group intervention versus a 'support as usual' waiting-list control group, with randomization at the level of the group. Outcomes will be assessed at the end of the intervention and again 6-months later. After completion of the 6-month follow-up assessments, the intervention will also be delivered to the waiting-list groups. The study will include a range of anger/aggression and mental health measures, some of which will be completed by service users and also by their day service key-workers and by home carers. Qualitative data will be collected to assess the impact of the intervention on participants, lay therapists, and services, and the study will also include a service-utilization cost and consequences analysis.

Discussion: This will be the first trial to investigate formally how effectively staff working in services providing day activities for people with learning disabilities are able to use a therapy manual to deliver a CBT based anger management intervention, following brief training by a Clinical Psychologist. The demonstration that service staff can successfully deliver anger management to people with learning disabilities, by widening the pool of potential therapists, would have very significant benefits in relation to the current policy of improving access to psychological therapies, in addition to addressing more effectively an important and often unmet need of this vulnerable client group. The economic analysis will identify the direct and indirect costs (and/or savings) of the intervention and consider these in relation to the range of observed effects. The qualitative analyses will enhance the interpretation of the quantitative data, and if the study shows positive results, will inform the roll-out of the intervention to the wider community.

Trial registration: ISRCTN: ISRCTN37509773

---

* Correspondence: P.Willner@swansea.ac.uk
[1]Directorate of Learning Disability Services, Abertawe Bro Morgannwg University Health Board, and Dept. of Psychology, Swansea University, UK
Full list of author information is available at the end of the article

Background

Cognitive behaviour therapy (CBT) is the treatment of choice for common mental health problems [1], and in the UK is recommended by the National Institute for Clinical Excellence (NICE) for this purpose. Widening access to CBT for people with mental health problems is seen as a major policy priority: the UK Department of Health has recently allocated £170 million to train 3600 CBT therapists in England through the Increasing Access to Psychological Therapies (IAPT) programme [2]. However, people with learning disabilities are unlikely to benefit from this development, as their particular needs have not been identified within the current policy and the necessary research on effectiveness for this population is still at a rudimentary stage. The diagnostic term 'learning disability' is used in the UK to refer to people who meet the World Health Organization definition of 'intellectual disability' ("significant impairments of both intellectual and functional ability, with age of onset before adulthood"), and is equivalent to the term 'mental retardation' as used until recently in the USA [3]. It is only recently that CBT has been adapted for people with learning disabilities, and the evidence of its effectiveness in this population consists largely of case studies and case series. There is a relatively large case-study literature describing successful outcomes for CBT in a variety of mental disorders [4-7]. However, the evidence from controlled trials is sparse.

The most developed evidence base is in relation to anger. Anger is a frequent problem for many people with learning disabilities. Although anger can exist without being expressed aggressively, anger in people with learning disabilities is typically associated with verbal and/or physical aggression [8]. Aggression is the main reason for an adult with a learning disability to be regarded as having severe challenging behaviour [9] and to be referred for resource intensive intervention [10]. Left unchecked, aggression resulting from uncontrolled anger can lead to serious consequences, which include exclusion from services, breakdown of residential placements, and in extreme cases, involvement with the criminal justice system [11-13]. Aggressive behaviour can also have an impact on the psychological well-being of staff [14] and the quality of care they provide [15]. Community services supporting adults with learning disabilities receive numerous referrals for anger problems: prevalence estimates for problem anger in the general population of people with learning disabilities vary between 11 and 27% [16]. A review of recent studies of aggressive challenging behaviour reported that over half of the population of people with learning disabilities display some form of aggression [17], and anger is highly prevalent in people labelled as having challenging behaviour: for example, Lindsay and Law (1999) reported that 60% of clients referred to a community service for people with learning disabilities and challenging or offending behaviours presented with clinically significant anger problems [18].

Challenging behaviour has traditionally been managed pharmacologically or behaviourally [19,20]. However, following the demonstration that a CBT anger management intervention can decrease anger and aggression [21-23], the past 20 years has seen an increasing take-up of anger management as the first-line approach to these problems. With the exception of two small controlled trials in depression [24,25], anger is the only psychological presentation in which controlled trials have been used to evaluate CBT interventions for people with learning disabilities. Several phase 2 trials have now been published in which CBT for anger has been compared with a waiting-list control condition. These include seven studies of anger management groups in community settings and one series of studies of individual treatment in a forensic setting [26], as well as a single study of individual therapy in a community setting [16]. However, these typically have been relatively small studies, and have not used fully randomized allocation to treatment [26,27]. The published studies are fully consistent in reporting that anger interventions are effective in helping people with learning disabilities to manage their anger better, and that treatment gains are maintained at three or six-month follow up [26]. There is also evidence that treatment gains generalize across settings. There is little information as to which are the crucial components of the intervention. However, one recent study reported a significant correlation between decreased anger reactivity and increased usage of anger coping skills, thus providing some evidence that the specific psycho-educational content of the anger management curriculum is intrinsic to its effectiveness [28].

A recent Cochrane review of interventions for aggressive behaviour in people with learning disabilities [27] identified only four studies suitable for inclusion, including one study of group-based CBT for anger [29] and one study of individual CBT for anger [30]. The review concluded that: *"The existing evidence on the efficacy of cognitive behavioural and behavioural interventions on outwardly directed aggression in children and adults with learning disabilities is scant. There is a paucity of methodologically sound clinical trials. Given the impact of such behaviours on the affected individual, his or her carers and on service providers, effective interventions are essential. It is also important to investigate cost efficacy of treatment models against existing treatments. We recommend that randomised controlled trials of sufficient power are carried out using primary outcomes of reduction in outward directed aggression, improvement in quality of life and cost efficacy as measured by standardised scales"* [27].

This trial will evaluate the effectiveness, compared to normal care, of a manualized anger management intervention, delivered to people with mild to moderate learning disabilities in a service setting and by service staff, in reducing levels of reported anger.

Methods/Design

Ethical and governance approval

Multi-centre approval has been granted by South East Wales Research Ethics Committee (**09/WSE03/41**). R&D approval has been granted in all regions, with additional participation identification centre approval where required. ISRCTN reference number is ISRCTN 37509773.

Design

This is a multi centre cluster randomized controlled trial of a manualized anger management group intervention versus a 'support as usual' waiting-list control group, with randomization of the group rather than the individual. A cluster randomized design, with one group per participating centre, was adopted to avoid the contamination between arms that would result if intervention and control groups were recruited within the same centre. The trial design is summarized in Figure 1

Sample size

Published studies of anger management in people with learning disabilities typically report large effect sizes. As service staff might be less effective therapists than psychologists, we aim to detect a medium-sized effect ($d = 0.57$). This estimate is a conservative 40% of the effect size ($d = 1.35$) observed in an earlier controlled trial using the same endpoint [31].

To achieve significance at $p < 0.05$ with 80% power will require two groups of $n = 72$ (allowing for ICC = 0.11). As there is no basis for estimating an ICC in the present context, we have used a value just above the range of ICC values reported in a recent systematic review [32], which varied between 0.01 and 0.1. This allows for the level of clustering that we would expect to see between participants naturally. As this is a group-based intervention, the effect in the intervention arm may well be to increase the degree of clustering. The analysis of the study will allow for this, but the sample has only been inflated to allow for the underlying level of clustering of service users within services rather than the component that relates to intervention effect.

To arrive at the target of 72 participants in each arm of the trial, a single group of 4-9 service users (average = 6) will be recruited in each of 30 participating centres. This total of 180 participants allows for 20% loss to follow-up, which is a conservative estimate: no drop-out was observed in two earlier studies conducted in day-service settings [31,28] and this is a relatively static population.

Service and participant recruitment

Thirty services providing day activities for people with mild to moderate learning disabilities will be recruited, on the basis that they report significant anger control problems among some of their service users. Within the current mixed-economy of care such services may be run by statutory or independent sector providers, and may vary in their mode of operation from traditional day centres to individualized community-based activity programmes. In order to recruit a sufficient number of centres within the time frame of the project, it is being implemented in three different regions, one in Wales, one in England and one in Scotland. In each region, 10 services will be identified, of which 5 will be randomly allocated to the intervention group and 5 to the control group. Within each group a minimum of 4 and a maximum of 9 service users will be recruited, which will mean a total of approximately 180 service users recruited on to the trial.

Potential service users are eligible for the trial if they meet all of the inclusion criteria and none of the exclusion criteria (Table 1).

Other participants

For each service user a key worker, and where applicable, a home carer will also be recruited (not all service users will have a home carer depending upon their residential setting). In each participating centre, at least two (wherever possible, three) staff will be recruited to act as lay therapists. Staff will be nominated by their manager and selected on the basis of their motivation to take on this role and their openness to use a cognitive behavioural approach, without reference to formal qualifications. Service Managers will also be recruited from each participating centre.

Randomisation

Randomisation will be performed using the method of minimisation [33,34]. Centres will be balanced on their service users' average baseline self-reported Provocation Index scores, the number of service users recruited and the average number of hours a week spent by the service user with at least one trainer outside of sessions. A random component, set at 80%, will be used alongside the minimisation procedure.

Centres will be recruited, and baseline data will have been collected on all participating service users (of a particular centre), before randomisation of that centre takes place.

Centres will be randomised using an automated service provided by SEWTU. Selection bias can be a problem in cluster-randomised trials if participants are

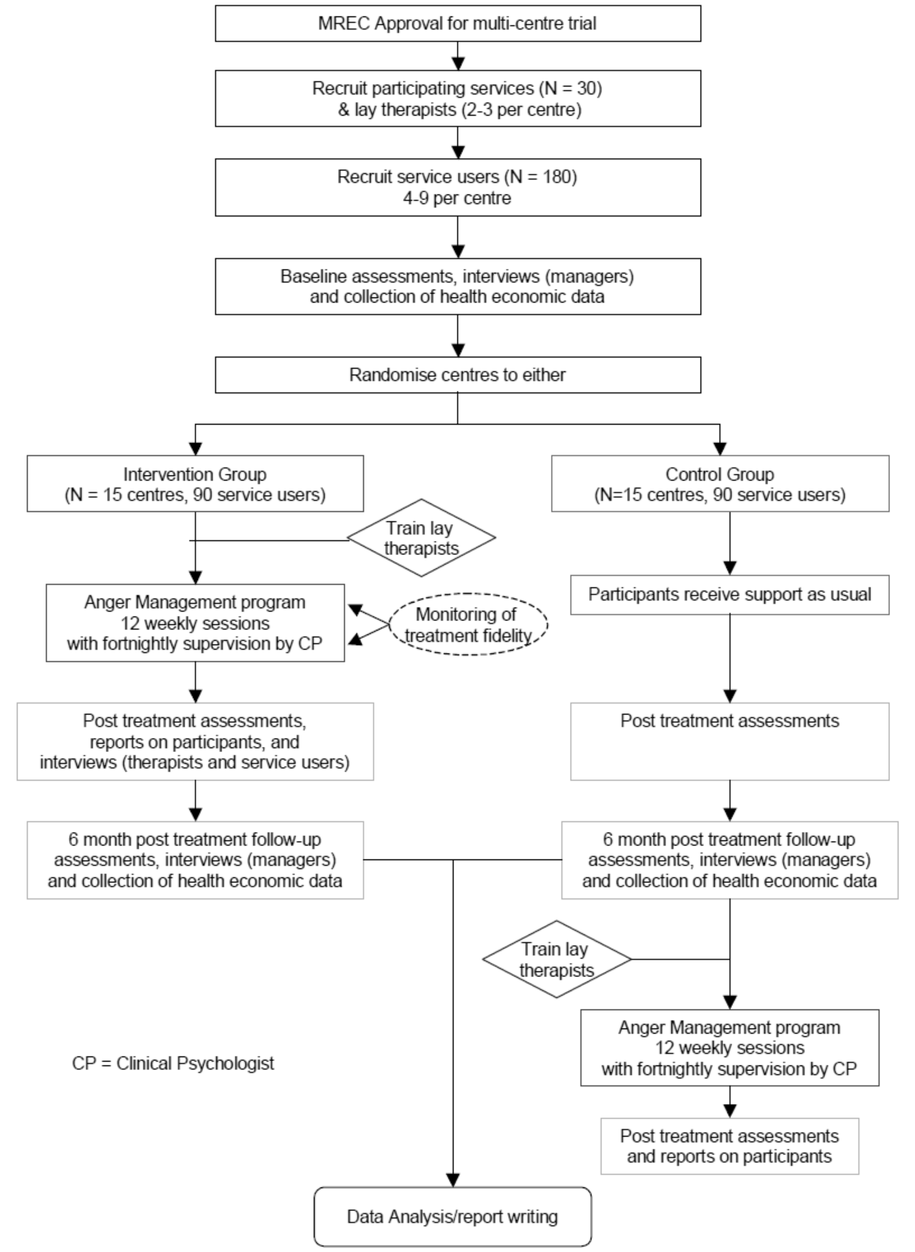


Figure 1 Trial Design.

recruited after cluster allocation has been revealed [35]. Therefore, all services and participants will be recruited and assessed prior to randomisation. In order to maintain engagement in services randomised to the control group, training is offered at the end of the study, and both groups will receive funding to cover the costs of replacing the staff who act as lay therapists. The research assistants who undertake the assessment of the outcomes will not have any involvement in the delivery of the intervention. As far as is possible they will be

Table 1 Inclusion and Exclusion Criteria

Inclusion criteria (Service Users)	Exclusion criteria (Service Users)
1. An adult attending a service for people with mild to moderate learning disabilities	1. Attending the service for a reason other than a diagnosed learning disability
2. Identified by service staff as having problems in managing their anger	2. Currently receiving psychological treatment for anger or aggression
3. Wishing to learn to improve their anger management	3. Urgently requiring referral to a Clinical Psychologist for individual treatment of anger or aggression
4. Able to provide informed consent	4. Experiencing circumstances which indicate that a Protection of Vulnerable Adults (POVA) procedure should be initiated
5. Able to complete the assessments	5. If for any other reason the supervising Clinical Psychologist makes a clinical judgement that participation in the group would be counter-indicated
Inclusion criteria (Services)	**Exclusion criteria (Services)**
1. Reported anger control problems among at least four service users who meet individual inclusion criteria and want to participate	1. The service is already running an anger management programme similar to this one
2. Availability of at least two staff members willing to be trained as group leaders	2. There are no suitable facilities for group work
3. The service manager will provide written agreement to participate	

blinded to the group allocation of the service, although during direct interaction with the service user the group allocation may become apparent. Where this occurs it will be recorded.

Trial procedures

Intervention

Participants will receive a manualized CBT intervention [28], consisting of 12 weekly psycho-educational group sessions supplemented by 'homework'. Before the start of the intervention, a Clinical Psychologist will provide the lay therapists with 2-3 training sessions, covering the principles of anger management and use of the therapy manual, followed by fortnightly supervision during the intervention. Additional training sessions could be provided, at the discretion of the trainer. Staff training will follow a training manual developed within the project for this purpose.

Topics addressed over sessions include: the triggers that evoke anger; physiological and behavioural components of anger; behavioural and cognitive strategies to avoid the build-up of anger and for coping with anger-provoking situations; and acceptable ways of displaying anger (assertiveness). Presentation relies heavily on brainstorming (e.g. "What makes us angry?") and role-play. After the first session, about a third of each session, is devoted to discussion by facilitators and group members of one or two participants' experiences, focussing primarily on problem solving around ways in which situations might have been handled differently to produce a better outcome. In addition to simplifying the language used in sessions, we avoid wherever possible the use of written materials, in favour of pictorial representations. Towards the end of every session, participants are asked to undertake a homework assignment, which consists of working with a staff member to complete a functional analysis ('hassle log'), of a situation in which they have been angered that week, which is described, analysed and evaluated, using a pictorial work-book. At the end of the intervention, reports are provided on each of the participants, and recommendations are made for further input by staff to maintain and increase treatment gains. A version of each report will also be produced in a format accessible to the service user.

Frequency and duration of follow up

All participants will be followed up post intervention, ie 16 weeks post randomisation and again 6 months later. The 16-week time point is chosen to allow two weeks before the start of the 12-week intervention for staff training, and two weeks to take account of likely delays due to centre closures or staff absences. After the 6-month follow-up the intervention will be delivered to the control group, followed by further post-intervention assessments (Figure 1): these data will be used in secondary analysis that are not described here.

A contractual agreement has been negotiated with participating services. Consent will be sought from five types of participants: the service users themselves, their key-workers and home carers, lay therapists and service managers. Written consent is taken from the service managers, lay therapists, key-workers and home carers, using consent forms and procedures that comply with standard Research Ethics Committee guidelines.

For service users, a more accessible consent procedure is used:

(i) The trial is explained verbally in simple terms, using a standard script written in accessible language, and checking frequently for understanding. It is important, when working with people with intellectual disabilities, to restrict the amount of information presented, so as to avoid information overload; therefore, the information script contains less information than might be usual with more able participants.

(ii) In addition to the general information sheet that is provided to all participants, service users are also given a simplified accessible information sheet, to take home and read in their own time and at their own speed, with support from carers (Figure 2)

(iii) At least two days are given to consider and ask questions of researchers or carers: long delays could be counter-productive in this client group.

(iv) The explanation is repeated in a second meeting.

(v) Consent is recorded by the service user checking and initialling a set of tick boxes and signing the consent form.

(vi) In order to assure that the service user has been properly informed, without coercion, the whole process is witnessed and signed off by a staff member who is independent of the research team.

For therapists and service users selected for interview after the end of the intervention (see below), a separate consent will be taken at the time, using the same procedures as above.

Outcome measures

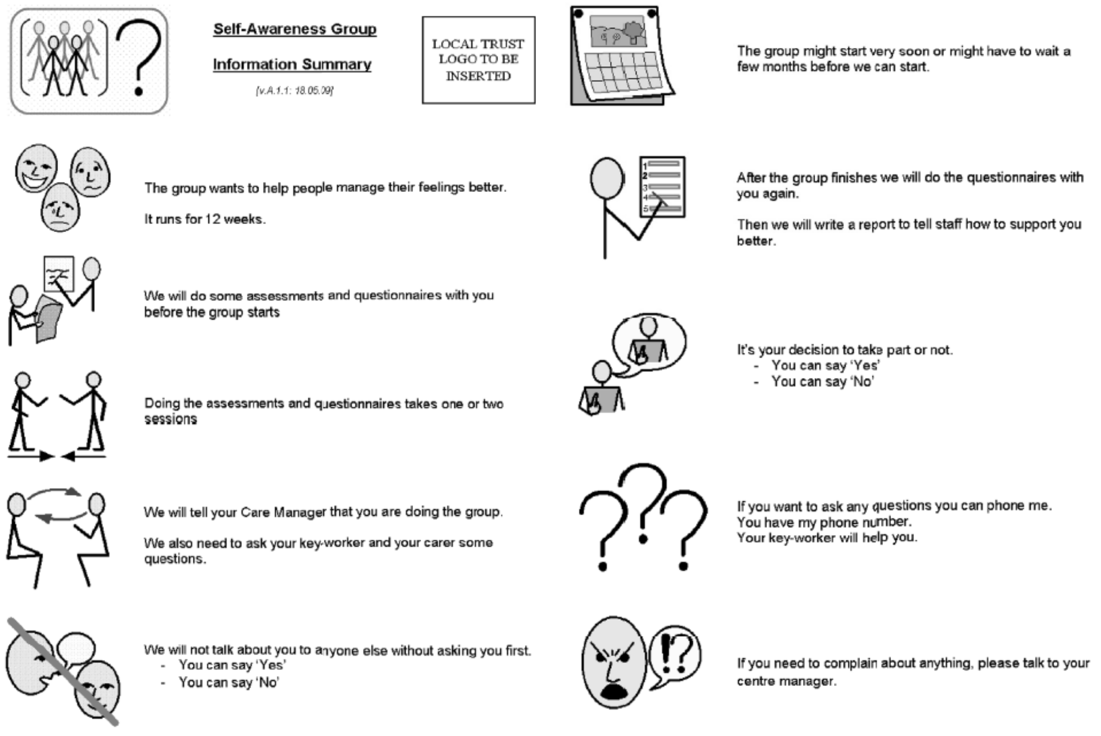
Quantitative assessments

An overview of the quantitative assessments is shown in Figure 3.

Participant Characteristics Intellectual and receptive language abilities will be assessed at baseline using the Wechsler Abbreviated Scale of Intelligence (WASI) and the British Picture Vocabulary Scale, 3rd edition (BPVS), respectively. Adaptive behaviour will be assessed using the short form of the Adaptive Behavior Scale [36], which is completed by the service-user's key-worker or home carer.

Quantitative Outcome Evaluation Quantitative measures will be administered before and after treatment and at 6-months after the end of treatment. The researchers undertaking these outcome assessments will not have any involvement in training or supervision of the therapists. They will undertake fidelity monitoring, but they will do this in a region other than the one where they conduct assessments.

Primary Outcome measure The main outcome measure will be the Provocation Index (PI) as completed by the service-user, at follow-up. The PI is a direct measure of felt response to defined situations that may provoke



Self-Awareness Group

Information Summary

[v.A.1.1: 18.05.09]

LOCAL TRUST LOGO TO BE INSERTED

The group wants to help people manage their feelings better.

It runs for 12 weeks.

We will do some assessments and questionnaires with you before the group starts

Doing the assessments and questionnaires takes one or two sessions

We will tell your Care Manager that you are doing the group.

We also need to ask your key-worker and your carer some questions.

We will not talk about you to anyone else without asking you first.
- You can say 'Yes'
- You can say 'No'

The group might start very soon or might have to wait a few months before we can start.

After the group finishes we will do the questionnaires with you again.

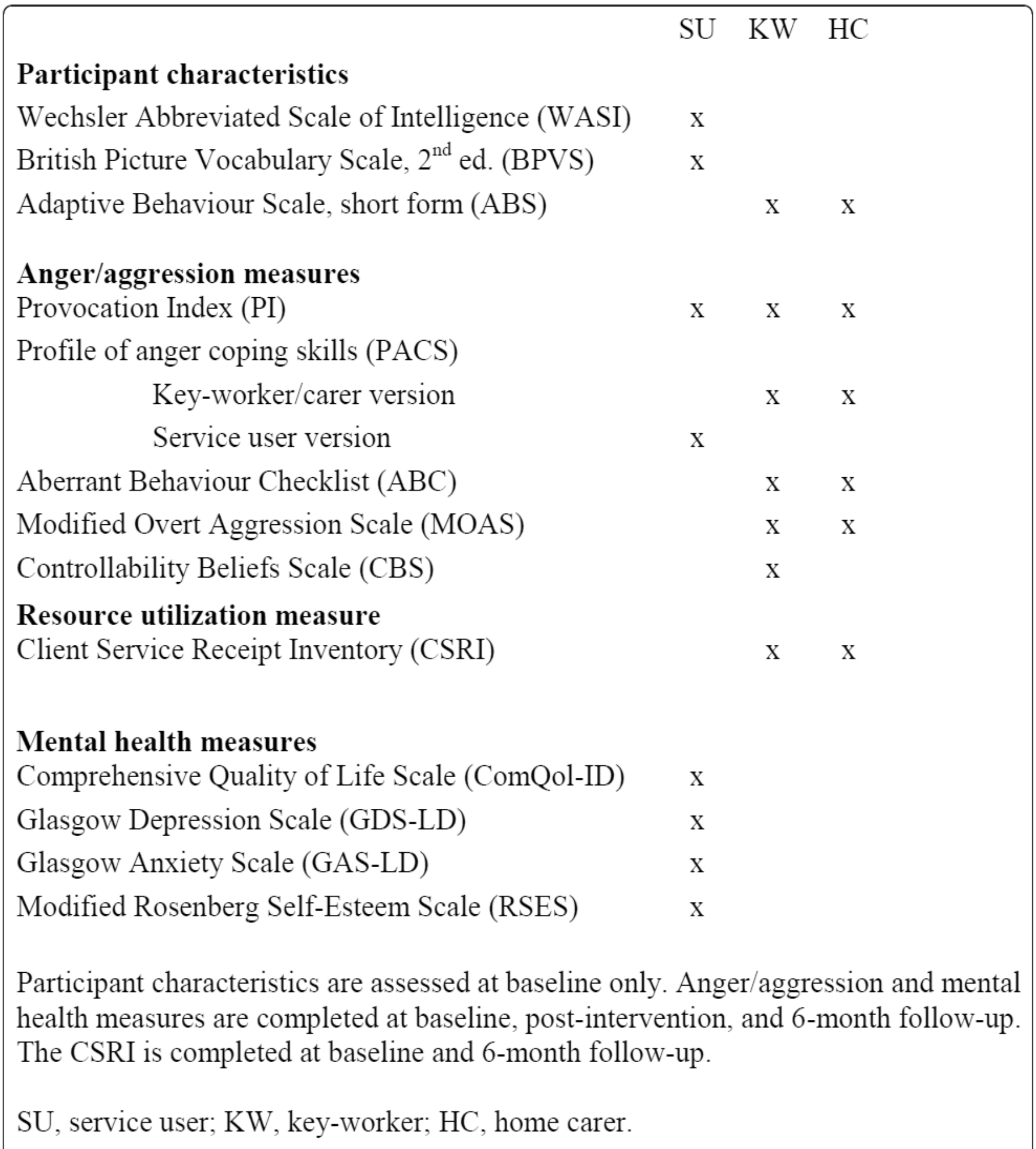
Then we will write a report to tell staff how to support you better.

It's your decision to take part or not.
- You can say 'Yes'
- You can say 'No'

If you want to ask any questions you can phone me.
You have my phone number.
Your key-worker will help you.

If you need to complain about anything, please talk to your centre manager.

Figure 2 Accessible information sheet.



	SU	KW	HC
Participant characteristics			
Wechsler Abbreviated Scale of Intelligence (WASI)	x		
British Picture Vocabulary Scale, 2nd ed. (BPVS)	x		
Adaptive Behaviour Scale, short form (ABS)		x	x
Anger/aggression measures			
Provocation Index (PI)	x	x	x
Profile of anger coping skills (PACS)			
Key-worker/carer version		x	x
Service user version	x		
Aberrant Behaviour Checklist (ABC)		x	x
Modified Overt Aggression Scale (MOAS)		x	x
Controllability Beliefs Scale (CBS)		x	
Resource utilization measure			
Client Service Receipt Inventory (CSRI)		x	x
Mental health measures			
Comprehensive Quality of Life Scale (ComQol-ID)	x		
Glasgow Depression Scale (GDS-LD)	x		
Glasgow Anxiety Scale (GAS-LD)	x		
Modified Rosenberg Self-Esteem Scale (RSES)	x		

Participant characteristics are assessed at baseline only. Anger/aggression and mental health measures are completed at baseline, post-intervention, and 6-month follow-up. The CSRI is completed at baseline and 6-month follow-up.

SU, service user; KW, key-worker; HC, home carer.

Figure 3 Overview of quantitative assessments.

anger that has frequently been used with this service-user group [37,8]. It consists of a list of 25 different situations that can evoke anger, each of which is rated on a four-point scale for the amount of anger that it would evoke. Scores on this measure have been shown to correlate with staff-reported levels of aggression [8].

Secondary Outcome measures Assessment will also involve completion of the PI by a key-worker [31,28]. For this and other measures, in the event that a service-user's key-worker is involved in the trial as a lay therapist, then the measure will be completed by another staff member.

Aggression will be assessed by key-worker report using the Irritability domain items of the Aberrant Behavior Checklist (ABC) [38] and the Modified Overt Aggression Scale (MOAS) [39]. Both assessments have been either designed or validated for assessment of people with learning disabilities, and were used to assess behaviour in a recent RCT of pharmacological treatment of aggressive challenging behaviour in adults with a learning disability [40]. Key-workers' attributions in respect of challenging behaviour will be measured by the Controllability Beliefs Scale (CBS) [41].

The Profile of Anger Coping Skills (PACS) [31,28] will be completed by both service-user and key-worker to assess the development of alternative, more functional coping skills.

Mental health will be assessed by using the Glasgow Depression and Anxiety Scales, which are established measures of depression and anxiety among people with a learning disability [42,43], and an adaptation of the Rosenberg Self-Esteem Scale for people with a learning disability [44]. Self-reported quality of life will be assessed by using the Comprehensive Quality of Life Scale - Intellectual Disability (ComQoL-ID) [45]. While it is predicted that successful acquisition of anger control skills might improve mental health and quality of life, these measures will also serve to detect adverse effects of treatment.

So as to assess generalization across settings, the anger, aggression and coping skills measures (PI, ABC, MOAS, PACS) will also be completed with service users' home carers, where appropriate.

Qualitative Assessments

One service user from each group (N = 15) will be interviewed after the intervention to gain an understanding of their experiences of participating in CBT. Service users will be randomly selected from a "short list" of those participants who are considered to have sufficient expressive language ability to be interviewed. This part of the research is not hypothesis driven but aims to gain an 'insider's perspective' from which a theoretical framework regarding the subjective experiences of service users can be developed.

The therapist who has been most active in terms of running each group (N = 15) will be interviewed post-intervention in order to investigate their experiences of learning and applying new therapeutic skills as cognitive behavioural therapists, as well as their impressions of the 'climate' within the group and the impact of the group on the wider service.

Both service user and therapist interviews will be conducted according to a semi-structured interview schedule, containing questions that encourage the participants to focus on 'personal meaning' and making sense of their experiences of the therapeutic process.

A related, but separate, part of the qualitative evaluation aims to gain an understanding of service policies and practices for service users who express anger inappropriately. This will be accomplished by interviewing the managers of all of the services in the intervention arm (N = 15), before the intervention and at follow-up.

Health-economic evaluation

The economic analysis will be in the form of a service-utilization cost and consequences analysis. The costing will be undertaken as follows;

1) All resources used in delivering the intervention will be recorded prospectively and valued using standard methods [46] with unit costs provided by the study sites. Resource inputs would include:

(i) Time input of (a) the applicants to train/supervise the clinical psychologists implementing and supervising the intervention, (b) the clinical psychologists in training and supervising the day service lay therapists running the groups, (c) the day service lay therapists in running the groups, (d) administrative/secretarial staff attributable to the intervention.

(ii) Travel costs attributable to the intervention.

(iii) Consumable costs attributable to the intervention (e.g. production of manuals).

2) All other resources used by study participants at the intervention sites, and all resources used by study participants at control sites will be monitored prospectively, using recording logs overseen by the research team. These will be valued using standard methods with unit costs provided by the study sites.

3) All relevant resource use, apart from that at the study sites, will be collected at baseline and at follow-up using the Client Service Receipt Inventory (CSRI). The CSRI is a validated tool to measure total package resource use and has been used in evaluations involving service users with psychiatric problems and service users with learning disabilities [47,48]. It records items such as contacts with community-based primary care, other health or social services, educational services, outpatient and inpatient attendances, etc. Unit costs for most of these are available [49]. Information will be collected from service-users' key-workers and/or home carers for the three-month period immediately preceding data collection.

In relation to (2) and (3) above, we propose specifically to investigate staff allocation within the provided services. Service managers will be interviewed to ascertain the staff-to-service-user ratios allocated to participants at baseline and at follow-up. As the national compendium cost figures give a breakdown of costs for day and residential services in which staff costs are identified, we will be able to adjust the staff cost element to reflect any changes in staff deployment between baseline and follow-up reported. Staff costs are the largest component of costs within day and residential services and arguably most likely to change as a result of treatment (e.g., in comparison with food, lighting, heating, estate, administrative and agency overhead costs).

Process Evaluation

An instrument to measure the fidelity of the intervention has been developed specifically for this trial. It measures therapists' adherence to the treatment manual and to the principles of cognitive behavioural therapy. In each centre, two sessions will be observed and recorded, by two members of the research team who have no other contact with that centre. The first observation will take place between week 3 and week 6 of the group and the second between week 7 and 10, with at least 3 weeks between the two observations.

Data analysis

Quantitative outcomes

The primary analysis will be intention to treat and will compare the mean self-reported PI between the two groups using a two level linear regression model, with participants at level 1 and centres at level 2, with baseline levels of the PI as a covariate. Secondary outcomes will be analysed similarly. Variables will be transformed prior to analysis if necessary to fulfil assumptions of normality.

Formal subgroup analysis of those who are above a threshold of self-reported PI of 1.0 at baseline, and those who meet formal criteria for a diagnosis of 'learning disability', will be undertaken through the fitting of interaction terms to the primary model. Other exploratory analysis will assess whether or not the effect of the intervention differs in different service settings (statutory/independent) and by intellectual and language ability.

A complier adjusted causal effect (CACE) will be estimated using a multi-level mixture analysis [50] to assess the impact of non-compliance with the intervention on the effect shown. A complier will be taken as someone who has attended at least two thirds of the sessions (8 of 12). None of the control group will be able to access the intervention until after follow-up is completed.

The associations between self and key worker/home carer reports will be assessed and compared between intervention and control groups. The association between anger coping skills and outcomes such as provocation, mental health and QoL will also be assessed. Secondary analyses to identify factors predictive of outcomes will be conducted using regression methods, based on the total cohort of N = 180, following delivery of the intervention to the control groups.

Qualitative outcomes

Service user interviews will be analyzed using Interpretative Phenomenological Analysis (IPA). IPA attempts to reduce the complexity of experiential data through vigorous and systematic analysis in a transparent and plausible manner [51]. It has a specific psychological focus and is suitable for data collected from less articulate/forthcoming participants. The focus of the therapist interviews is on the therapists' personal, subjective experiences and therefore IPA will again be utilised as the most appropriate qualitative analysis.

As the focus of the service manager demands a structured, factual line of enquiry, Thematic Analysis (TA) [52] will be used to categorise participants' responses into themes and sub-themes. Responses will be grouped according to each of the questions posed during the structured interview and will be analysed as such, in order to establish common themes and differences within and between services before and after the intervention. A particular focus of this part of the evaluation will be the perceived influence that the CBT trials have had on professional practice within each of the services.

Both of the qualitative evaluations (IPA and TA) will be subjected to a credibility check, by presenting relevant participants with a summary account of the findings in order to establish whether the analyses have produced an account which is credible and comprehensible to its informants.

Health economic outcomes

The analysis is directed at addressing three inter-related questions: (a) the extent to which there is added resource usage above support as usual arising from providing the intervention, (b) the extent to which service package costs at follow-up differ from those at baseline, and (c) if both a and b reveal differences in hypothesised directions, the extent to which additional costs might be offset by subsequent savings in ongoing support. (Clearly, it will be redundant to conduct this third stage if the intervention is cheaper to provide than support as usual and results in reduced service package costs or if the intervention is more expensive to provide than support as usual and results in greater service package costs.)

In principle, the cost data will not be treated differently from other data in the analysis. Cost data are frequently skewed. Tests for normality will be applied. If the distribution of data is shown to be non-normal, non-parametric bootstrapping methods will be used to test for differences in costs between groups [53]. Bootstrapping produces a confidence interval for the difference between the means and significance is judged by whether the confidence interval contains zero. Specifically, if the confidence interval does not contain zero, it is assumed that the difference between the means is significant. Bootstrapping does not produce a conventional test statistic by which the level of significance can be judged. Confirmatory, post-hoc, non-parametric testing can be performed to obtain conventional significance levels.

We are primarily reliant on the research to establish associations between the intervention and outcomes including cost. However, we will also attempt to interpret cost changes found. For example, were there to be changes in staff allocation post treatment, we would ask service managers to say what underlay this change, or, if a person moved from living in the family home to an out-of-family placement, we would find out the reason (e.g., did it relate to the person's behaviour or had family capacity to provide care diminished).

Discussion

This will be the first multi-centre trial to investigate formally how effectively staff working in services providing day activities for people with learning disabilities are able to use a therapy manual to deliver a CBT-based anger management intervention, following brief training by a Clinical Psychologist. The study incorporates a wider range of outcome measures than previous studies, and includes an analysis of the cost consequences of delivering the intervention. The demonstration that service staff can successfully deliver anger management to people with learning disabilities would have very significant benefits in relation to the current policy of improving access to psychological therapies, by widening the pool of potential therapists, in addition to addressing more effectively an important and often unmet need of this vulnerable client group. Some scepticism has been expressed about whether it is feasible to undertake randomised controlled trials of psychological interventions for people with learning disabilities [54]. The successful implementation of this RCT would serve to allay these doubts and encourage further research to strengthen the evidence base for interventions to support this population. We hope also to identify factors relating to characteristics of participants or settings that are associated with differential outcomes. The study will also pilot a fidelity-monitoring instrument that is not anger specific, but rather, has been designed to be applicable to any CBT-based group therapy for people with learning disabilities.

Felce et al. (2003) found that 26% of the variance in staff costs per person in residential services was associated with scores on a challenging behaviour measure (the Aberrant Behavior Checklist) that we are using as one of our outcome measures [55]. The service-utilization cost and consequences analysis will determine the extent to which delivering the intervention incurs resource inputs over and above support as usual, and whether successful reduction of anger and aggression is associated with any change in subsequent resource use. We rejected a cost utility approach because we believe that the utility-based health state measures such as EQ-5D required for such analyses would not be sensitive to the effects anticipated from the intervention. We rejected a cost effectiveness approach partly because of the multiple objectives of the intervention (e.g. aggression, controllable beliefs, coping, self esteem), which cost effectiveness analysis cannot handle, and partly because the primary outcome measure, the provocation index (PI), is not an effect that features in economic analyses of related interventions. Unless our intervention is shown to be dominant (more effective and less costly than usual care) then an incremental cost effectiveness ratio in terms of extra cost per unit PI would be of little value in informing policy. The proposed cost and consequences analysis is, strictly, not a technique of economic evaluation as it cannot provide a definitive answer to questions of either allocative or technical efficiency. It does however identify the direct and indirect costs (and/or savings) of the intervention and considers these in relation to the range of observed effects.

We anticipate that the qualitative data will enhance the quantitative analyses in four distinct ways. First, as with any well-designed mixed-methods study, we will aim to generate a productive interaction between the quantitative and qualitative analyses: exploratory quantitative analysis will be undertaken to explore possible inter-relationships between factors identified in the qualitative analysis; similarly the qualitative data will be reviewed to explore evidence in relation to findings that emerge from the quantitative modelling. Second, while the quantitative data will provide answers to the question of the effectiveness of the intervention, they will not provide insights into the process or mechanisms of change. This information will, however, emerge from an account of the participants' (both service users and staff) experience of the groups and their understanding of the intervention. The qualitative findings will also influence the interpretation of the outcome data by indicating the personal salience (as distinct from the statistically significance), for clients or those affected by their behaviour, of any changes that are found. And if there are negative results, the qualitative data, alongside the assessment of the fidelity of intervention delivery, may help to explain them. Third, interviewing participants and staff may identify unanticipated outcomes of the group, either positive or negative, and barriers to change. (For example, in a study of anger management by adolescents, qualitative analysis identified some clinically important but unanticipated moderating effects of participants' ages on outcomes, which were confirmed in a reanalysis of the quantitative data: [56].) Finally, if the study shows positive results, the qualitative data, including the impact of the intervention on the culture within day services, will inform the roll-out of the intervention to the wider community.

Acknowledgements

This project is funded by the NIHR Health Technology Assessment programme and will be published in full in the Health Technology Assessment journal series. Visit the HTA programme website for more details http://www.hta.ac.uk/. The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the Department of Health. The South East Wales Trials Unit is funded by the National Institute for Health & Social Care Research.

Cardiff University is the sponsor for this trial

Professor David Cohen, University of Glamorgan, is a consultant to the project on Health Economics

Dr Aimee Stimpson, ABM ULHB, Dr Nicola Rose, Dudley PCT, and Dr Pamela MacMahon, Glasgow University, are the clinical psychologists responsible for conducting the trial in each of the three regions, and contributed to the design of the qualitative and process assessments.

Author details

[1]Directorate of Learning Disability Services, Abertawe Bro Morgannwg University Health Board, and Dept. of Psychology, Swansea University, UK. [2]Psychological Medicine, University of Glasgow, Gartnaval Royal Hospital, Glasgow, UK. [3]Psychology Department, University of Birmingham, UK. [4]South East Wales Trials Unit, Department of Primary Care & Public Health, School of Medicine, Cardiff University, Cardiff, UK. [5]Psychological Medicine, School of Medicine, Cardiff University, Cardiff, UK.

Authors' contributions

PW is the Principal Investigator and led the study design and funding application, and the writing of this manuscript. AJ and JR are clinical psychologists who contributed to the study design and funding application, particularly in relation to the clinical intervention and quantitative outcome measures. BSK is a clinical psychologist who contributed to the study design and funding application, particularly in relation to the qualitative analyses. DF is a health services researcher who contributed to the study design and funding application, particularly in relation to the health economic evaluation. JN is the senior trial manager and JT is the trial manager and both contributed to the study design, management and analysis plan. DG is the trial statistician and contributed to the study design and analysis plan. KH is the senior statistician and contributed to the study design and analysis plan, and to the funding application and is the responsible individual to the sponsor. All authors contributed to, read and approved the final version of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Received: 25 November 2010 Accepted: 9 February 2011
Published: 9 February 2011

References

1. Roth A, Fonagy P: **What works for whom? A critical review of psychotherapy research.** Guilford Press, New York, 2 2004.
2. DoH/CSIP: **Choices in Mental Health: Improving Access to Psychological Therapies.** 2007 [http://www.dh.gov.uk].
3. British Psychological Society: **Learning Disability: Definitions and Contexts.** British Psychological Society, Leicester; 2000.
4. Lindsay WR: **Cognitive therapy.** *Psychologist* 1999, **12**:238-241.
5. Hatton C: **Psychosocial interventions for adults with intellectual disabilities and mental health problems: A review.** *J Ment Health* 2002, **11**:357-373.
6. Willner P: **Readiness for cognitive therapy in people with intellectual disabilities.** *J App Res Intellect Disabil* 2005, **19**:5-16.
7. Taylor JL, Lindsay WR, Willner P: **CBT for people with intellectual disabilities: Emerging evidence, cognitive ability and IQ effects.** *Behavioural and Cognitive Psychotherapy* 2008, **36**:723-734.
8. Taylor JL, Novaco RW: **Anger Treatment for People with Developmental Disabilities: A Theory, Evidence and Manual-Based Approach.** Wiley, Chichester; 2005.
9. Allen D, Felce D: **Service responses to challenging behaviour.** In *Psychiatric and behavioural disorders in developmental disabilities.* Edited by: Bouras N. Cambridge: Cambridge University Press; 1999.
10. Lowe K, Felce D, Blackman D: **People with learning disabilities and challenging behaviour: the characteristics of those referred and not referred to specialist teams.** *Psychol Med* 1995, **25**:595-603.
11. Allen D, Lowe K, Brophy S, Moore K: **Predictors, costs and characteristics of out of area placements for people with intellectual disability and challenging behaviour.** *J Intellect Disabil Res* 2007, **51**:409-416.
12. Emerson E, Robertson J, Dorr H, Russell P, Spencer K, Davies I, Felce D, Allen D, Churchill J, Rose S, Maguire S, Hatton C, Madden P, Mills R, McIntosh B, Congdon D: **Commissioning Person Centred, Cost Effective, Local Support for People with Learning Difficulties.** London: Social Care Institute for Excellence; 2008.
13. Mental Health Foundation Boiling Point: 2008 [http://www.mentalhealth.org.uk].
14. Jenkins R, Rose J, Lovell C: **Psychological well-being of staff working with people who have challenging behaviour.** *J Intellect Disabil Res* 1997, **41**:502-511.
15. Rose J, Jones F, Fletcher B: **Investigating the relationship between stress and worker behaviour.** *J Intellect Disabil Res* 1998, **42**:163-172.
16. Rose J, Dodd L, Rose N: **Individual cognitive behavioural intervention for anger.** *J Ment Health Res Intellect Disabil* 2008, **1**:97-108.
17. Benson BA, Brooks W: **Aggressive challenging behaviour and intellectual disability.** *Curr Opin Psych* 2008, **21**:454-458.
18. Lindsay WR, Law J: **Outcome evaluation of 161 people with learning disabilities in Tayside who have offending or challenging behaviour, 1999.** *Paper presented to British Association for Behavioural and Cognitive Psychotherapy, 27th Annual Conference* Bristol; 1999.
19. Didden R, Duker P, Korzilius H: **Meta-analytic study on treatment effectivesness for problem behaviours in individuals who have mental retardation.** *Am J Ment Retard* 1999, **101**:387-399.
20. Matson J, Bamburg J, Mayville E, Pinkston J, Bielecki J, Kuhn D, *et al*: **Psychopharmacology and mental retardation: A ten year review (1990-1999).** *Res Dev Disabil* 2000, **21**:263-296.
21. Benson BA, Rice CJ, Miranti SV: **Effects of anger management training with mentally retarded adults in group treatment.** *J Consult Clin Psychol* 1986, **54**:728-279.
22. Benson B: **Teaching anger management to persons with mental retardation.** Champaign, IL: International Diagnostic System, Inc; 1992.
23. Benson B: **Anger management training: A self control program for people with mild mental retardation.** In *Mental Health in Mental Retardation.* Edited by: Bouras N. Cambridge, UK: Cambridge University Press; 1994:224-232.
24. McCabe MP, McGillivray JA, Newton DC: **Effectiveness of treatment programmes for depression among adults with mild/moderate intellectual disability.** *J Intellect Disabil Res* 2006, **50**:239-247.
25. McGillivray JA, McCabe MP, Kershaw MM: **Depression in people with intellectual disability: An evaluation of a staff-administered treatment program.** *Res Dev Disabil* 2008, **29**:524-536.
26. Willner P: **CBT for people with intellectual disabilities: Focus on anger.** *Adv Ment Health Learn Disabil* 2007, **1**:14-21.
27. Hassiotis I, Hall I: **Behavioural and cognitive-behavioural interventions for outwardly-directed aggressive behaviour in people with learning disabilities.** *Cochrane Database Syst Rev* 2008, CD003406.
28. Willner P, Tomlinson S: **Generalization of anger-coping skills from day-service to residential settings.** *Journal of Applied Research in Intellectual Disabilities* 2007, **20**:553-562.
29. Willner P, Jones J, Tams R, Green G: **A randomised controlled trial of the efficacy of a cognitive-behavioural anger management group for adults with learning disabilities.** *J App Res Intellect Disabil* 2002, **15**:224-235.
30. Taylor JL, Novaco RW, Gillmer BT, Robertson A, Thorne I: **Individual cognitive-behavioural anger treatment for people with mild-borderline intellectual disabilities and histories of aggression: A controlled trial.** *Brit J Clin Psychol* 2005, **44**:367-382.
31. Willner P, Brace N, Phillips J: **Assessment of anger coping skills in individuals with intellectual disabilities.** *J Intellect Disabil Res* 2005, **49**:329-339.

32. Eldridge SM, Ashby DS, Feder GSR, Rudnicka AR, Ukoumunne OC: **Lessons for cluster randomized trials in the twenty-first century: a systematic review of trials in primary care.** *Clin Trials* 2004, **1**:80-90.
33. Scott NW, McPherson GC, Ramsay CR, Campbell MK: **The method of minimization for allocation to clinical trials: a review.** *Controlled Clinical Trials* 2002, **23**:662-674.
34. Altman DG, Bland JM: **Treatment allocation by minimisation.** *BMJ* 2005, **330**:843.
35. Puffer S, Torgerson D, Watson J: **Evidence for risk of bias in cluster randomised trials: a review of recent trials published in three general medical journals.** *British Medical Journal* 2003, **327**:785.
36. Hatton C, Emerson E, Robertson J, Gregory N, Kessissoglou S, Perry J, Felce D, Lowe K, Walsh PN, Linehan C, Hillery J: **The Adaptive Behavior Scale - Residential and Community (Part I) - Development of a short form.** *Res Dev Disabil* 2001, **22**:273-288.
37. Novaco RW: **Anger as a risk factor for violence among the mentally disordered.** In *Violence and Disorder: Developments in Risk Assessment.* Edited by: Monahan J, Streadman HJ. Chicago: University of Chicago Press; 1994:21-59.
38. Aman MG, Singh NN, Stewart AW, Field CJ: **The Aberrant Behavior Checklist: a behavior rating scale for the assessment of treatment effects.** *Am J Ment Defic* 1985, **89**:485-91.
39. Oliver PC, Crawford MJ, Rao B, Reece B, Tyrer P: **Modified Overt Aggression Scale (MOAS) for people with intellectual disability and aggressive challenging behaviour: a reliability study.** *J App Res Intellect Disabil* 2007, **20**:368-72.
40. Tyrer P, Oliver-Africano PC, Ahmed Z, Bouras N, Cooray S, *et al*: **Risperidone, haloperidol, and placebo in the treatment of aggressive challenging behaviour in patients with intellectual disability: a randomised controlled trial.** *Lancet* 2008, **371**:57-63.
41. Dagnan D, Grant F, McDonnell A: **Understanding challenging behaviour in older people: The development of the controllability beliefs scale.** *Behav Cog Psychother* 2004, **32**:1-6.
42. Cuthill FM, Espie CA, Cooper S-A: **Development and psychometric properties of the Glasgow Depression Scale for people with a learning disability: Individual and carer supplement versions.** *British Journal of Psychiatry* 2003, **182**:347-353.
43. Mindham J, Espie CA: **Glasgow Anxiety Scale for people with an Intellectual Disability (GAS-ID): development and psychometric properties of a new measure for use with people with mild intellectual disability.** *J Intellect Disabil Res* 2003, **47**:22-30.
44. Dagnan D, Sandhu S: **Social comparison, self-esteem and depression in people with intellectual disability.** *Journal of Intellectual Disability Research* 1999, **43**:372-379.
45. Cummins RA: **The Comprehensive Quality of Life Scale: Intellectual Disability.** Melbourne, Australia: Deakin University, 5 1997.
46. Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G: **Methods for the Economic Evaluation of Programmes in Health Care.** Oxford University Press. Oxford, 3 2005.
47. Beecham J: **Collecting and estimating costs.** In *The Economic Evaluation of Mental Health Care.* Edited by: Knapp MRJ. Aldershot: Arena; 1995.
48. Beecham J, Knapp MRJ: **Costing psychiatric interventions.** In *Measuring Mental Health Needs.* Edited by: Thornicroft GJ, Brewin CR, Wing JK. London: Gaskell; 1992.
49. Curtis L: **Unit Costs of Health and Social Care 2008.** PSSRU; 2008.
50. Jo B, Asparouhov T, Muthen B: **Intention-to-treat analysis in cluster randomised trials with non-compliance.** *Statistics in Medicine* 2008, **27**:5565-5577.
51. Smith JA: **Beyond the divide between cognition and discourse: using interpretative phenomenological analysis in health psychology.** *Psychology & Health* 1996, **1**:39-54.
52. Aronson J: **A pragmatic view of thematic analysis.** *The Qualitative Report* 1994, **2**:131-134, 1994.
53. Efron B, Tibshirani R: **An Introduction to the Bootstrap.** New York: Chapman and Hall; 1993.
54. Oliver PC, Piachaud J, Done J, Regan A, Cooray S, Tyrer P: **Difficulties in conducting a randomised controlled trial of health service interventions in intellectual disability: implications for evidence-based practice.** *J Intellect Disabil Res* 2002, **46**:340-345.
55. Felce D, Jones E, Lowe K, Perry J: **Rational resourcing and productivity: Relationships among staff input, resident characteristics and group home quality.** *Am J Ment Retard* 2003, **108**:161-172.
56. Down R, Willner P, Watts L, Griffiths J: **Anger management groups for adolescents: A pilot study using quantitative and qualitative methods.** *Clinical Child Psychology and Psychiatry* 2011, **16**:33-52.

doi:10.1186/1745-6215-12-36
Cite this article as: Willner *et al.*: **Anger management for people with mild to moderate learning disabilities: Study protocol for a multi-centre cluster randomized controlled trial of a manualized intervention delivered by day-service staff.** *Trials* 2011 **12**:36.

Appendix 2 Unit costs

TABLE 61 Day activities unit costs and sources

Day activity	Unit costs (£)	Notes (source: Curtis[105] unless otherwise stated)
LA day centre/social club/recreation	22.40/hour	£56 per session (am/pm/evening) LA day care for those with learning difficulties. Session approximately 2.5 hours = £22.40/hour
NHS day care	35.20/hour	NHS day care mental health = £33 per session LA day care mental health = £21 per session Estimate NHS day care for LD = 33 × 56 (LA day care LD)/21 (LA day care MH) = £88 per session/2.5 = £35.20/hour
Voluntary sector day care	22.40 hours	Voluntary day care MH = £21 per session LA day care MH = £21/session As voluntary = LA in MH, by the same token, voluntary day care in LD = LA = £22.40/hour
Private day care	17.80/hour	Rehabilitation centre for brain injured (private) £89 per day: £44.50 per session/2.5 = £17.80/hour
Sheltered work	7.80/hour	Sheltered work mental health net costs = £7.80/hour
Voluntary work	22.40/hour for LA and voluntary 17.80/hour for private	Assume run under the auspices of the day centre; therefore, similar range of costs
Adult education	19.89/hour	Average annual cost/adult with autism (2005–6 prices) = £2886 per annum[212] Average hours/week from CSRI = approximately 3 hours/week £2886/52/3 = £18.50/hour (uplift 2008[213] = 2.9%, 2009 = 3.9%, 2010 = 0.6%) = £19.89/hour
Drop-in centre/social club	10.57/hour	Average cost/week for intellectual disability and challenging behaviour. Drop-in centres £9.14/week.[214] Average hours/week from CSRI = approx. 1 hour/week = £9.14/hour (uplift 2006[213] = 3.7%, 2007 = 3.7%, 2008 = 2.9%, 2009 = 3.9%, 2010 = 0.06%) = £10.57/hour
One-to-one activity/supported employment	25.00/hour	LA home care worker: unit cost £25.00/hour (f2f week-day contact)

f2f, face to face; LA, local authority; LD, learning disabilities; MH, mental health.

TABLE 62 Hospital-based services unit costs and sources

Service	Unit costs (£)	Notes (source: Curtis[105] unless otherwise stated)
Psychiatric intensive care ward overnight	585.00	National average intensive care: adults = £585 per patient-day (p. 119)
Acute psychiatric ward overnight	295.00	National average acute care: adults = £295 per inpatient-day (p. 119)
Psychiatric long-stay ward overnight	271.00	National average rehabilitation: adults = £271 per inpatient-day (p. 119)
General medical ward overnight	238.42	Curtis (2007):[215] cost/bed per day for inpatient rehabilitation services – weighted average all stays £223 (uplift 2008[213] = 2.9%, 2009 = 3.9%, 2010 = 0.06%) = £238.42
Other specialities overnight	252.75	Curtis (2007):[215] inpatient rehabilitation services (cost/bed/day): non-stroke/elderly £235 (uplift 2008[213] = 2.9%, 2009 = 3.9%, 2010 = 0.06%) = £252.75
Psychiatric outpatient appointment	158.00	MH outpatient attendances, consultant services (follow-up f2f attendances): adult other services £158
Other hospital outpatient/clinic appointment	152.00	Outpatient procedures (non-MH) – weighted average for all £152
Day hospital attendance	144.00	Day facilities (non-MH) – weighted average for all £143 in Curtis (2009)[216] – 2010 uplift[213] = 0.06% = £144
Psychiatric day hospital attendance	119.00/day	MH day care weighted average of all attendances £119
Accident & Emergency attendance	114.00	Treatments leading to admission £131 Treatments not leading to admission £97 Average £114

f2f, face to face; MH, mental health

TABLE 63 Community-based services unit costs and sources

Service	Unit costs (£)	Notes (source: Curtis unless otherwise stated)
Community psychiatrist	328.00/hour (f2f)	Consultant (psychiatric) £328/hour (patient contact)
Psychologist	81.00/hour	Clinical psychologist £81 per hour of client contact
General practitioner	185.00/hour: clinic	£36/11.7 minutes or £53/17.2 minutes of surgery consultation Mean = £3.10/minute × 60 = £185/hour surgery/clinic
	312.00/hour: home	£120/23.4 minute home visit £5.20/minute × 60 = £312/hour home visit
CMHT member, learning disability/psychiatric nurse	91.00/hour	Community nurse specialist £91/hour f2f
Other community nurse	73.00/hour	Community nurse £73/hour f2f
Health care assistant	23.00/hour	Clinical support worker (hospital) £23/hour (patient contact)
Health visitor	88.00/hour	£88 per hour of client contact
Therapists: speech, physiotherapy, occupational, art/drama/music, alternative (e.g. massage, aromatherapist)	42.00/hour (f2f) 34.00/hour (clinic) 44.00/hour (home visit)	£42/hour (client contact); £34/hour (in clinic); £44/hour (home visits); £47/home visit; £17/clinic visit
Social worker, care manager	87.00/hour 150.00/hour (f2f)	Social work team leader £87/hour client-related work Approved social worker (MH) £150/hour (f2f)
Social work assistant	33.00/hour	Social work assistant £33/hour (client related); £103/hour (f2f)
Advocate counsellor, LD charity representative, appropriate adult	44.00/hour (f2f)	Counselling services in primary care £44/hour f2f

continued

TABLE 63 Community-based services unit costs and sources (*continued*)

Service	Unit costs (£)	Notes (source: Curtis unless otherwise stated)	
Dentist	Consultant 309.00/hour	Medical consultant £120,200: unit cost £169/hour, ratio salary/unit cost = £711.2. Salary + expenses (see below) = £219,789: unit cost = £309/hour	
	Independent 272.00/hour	Independent gross income 2007–8:[217] £193,480 (income £93,891, expenses £99,589); total/711.2 = 272/hour	
	Band A 206.00/hour	Salaried dentist: Band A:[217] minimum £37,718, maximum £56,576	Mid-point + expenses/711.2 = 206/hour (A), 203/hour (B), 246/hour (C)
	Band B 230.00/hour	Salaried dentist: Band B:[217] minimum £58,672, maximum £68,625	
	Band C 246.00/hour	Salaried dentist: Band C:[217] minimum £70,197, maximum £80,674	
Optician, audiologist	41.40/hour	DH[218] – fee payable by PCT to the general ophthalmic service contractor for each sight test = £20.70. Assume average appointment = 30 minutes (£41.40/hour)	
Chiropodist	22.00/hour	Community chiropodist/podiatrist £22/hour	
NHS Care Manager	112.00/hour	Intensive case management for older people £112/hour (f2f contact); £36/home visit	
GP nurse	36.00/hour	GP nurse £36/hour client contact	
Job Centre	62.48/hour	Job Centre Plus Annual Report & Accounts 2010–11:[a] Total expenditure = £3,570,942,000 Total staff = 76,471 ● Assume 67% of staff provide f2f services = 51,236. Each works 45 weeks × 37 hours/week (Green Book[218]) = 1665 hours/year Total staff hours of f2f services = 85,307,940 hours ● Assume 67% of time in actual f2f services = 57,156,320. Cost/hour = £62.48	
Police	57.50/hour	£172.51 Heslin *et al.* (2011):[219] 3 hours of input = £57.50/hour £55.42/hour City of London police hourly rate[b]	
Dietitian	29.00/hour	£29 per hour of client contact	

CMHT, Community Mental Health Team; f2f, face to face; LHB, local Health Board; MH, mental health; PCT, Primary Care Trust.

[a] Source: http://www.dwp.gov.uk/docs/jcp-annual-report-and-accounts-2010-2011.pdf (accessed 4 April 2013).

[b] Source: www. cityoflondon.police.uk/CityPolice/About/services/feesandcharges.htm (accessed 17 February 2012).

TABLE 64 Unit costs and sources for accommodation services, respite, day care staff and domiciliary support staff

Accommodation or staff input	Unit costs (£)	Notes (source: Curtis[105] unless otherwise stated)
Fully staffed group homes	935.00/week staff 260.00/week non-staff	Staffing £935 per resident week; £1195 establishment costs per resident week; non-staff costs (establishment – staff) = £260 per resident week
Semi-independent living	255.00/week staff 130.00/week non-staff	Staffing £255 per resident week; £385 establishment costs per resident week; non-staff costs (establishment – staff) = £130 per resident week
Hospital	969.00/week staff 409.00/week non-staff	NHS campus (2004–5) Curtis (2005):[220] staffing £843 per resident week; £1198 establishment costs per resident week × 1.15 (increase since 2004–5, p. 224, table 4, Curtis 2010):[105] staffing £969 per resident week; £1378 establishment costs per resident week; non-staff costs (establishment – staff) = £409 per resident week
Independent sector residential care staff rates[a]	12.91/hour	Support worker £9.42/hour with 30% on-cost Assistant service manager £11.18/hour with 30% on-cost Service manager £14.90 with 30% on-cost ● Mean of first two = £12.91/hour
NHS staff costs	14.05/hour	Band 7: £21.93/hour Band 6: £18.30/hour Band 5: £15.19/hour Band 3: £10.62/hour ● Weighted average (8% each Bands 6 and 7 + 42% each Bands 3 and 5) = £14.05/hour
LA support worker		Local Government Earnings Survey 2010–11 Observed Pay Rates:[221] ● Care worker median £19,620 gross = £436.00/week, £11.78/hour ● Senior care worker median £23,386 gross = £519.69/week, £14.04/hour [converted using working hours/week = 37, weeks worked/year = 45 (Green Book[222])]
LA day service staff[b]	14.10/hour front line	Day support workers (£14,733–16,830): mean = £15,781.5 Day service officers (£18,453–22,221): mean = £20,337 ● Mean of above two = 18,059 × 1.3 (30% on-costs) = £23,476.7, £14.10/hour
	21.74/hour manager	Service manager (£27,052–28,636): mean = £27,844 × 1.3 (30% on-cost) = £36,197, £21.74/hour
Area homes manager	21.74/hour	As LA service manager
Finance officer	15.56/hour	NHS Band 4 mid-point = £19,933 × 1.3 (on-cost) = £25,913, £15.56/hour
Facility-based respite	170.71/day	£1195 establishment costs per resident week for fully-staffed group homes = £170.71/day
Adult family placement	435.76/week	2008 'All-in' long-term placement including board and lodging: mean = £419/week, including £58/week management charge, NAAPS (2009)[223] × 1.04 increase since 2007–8 (see Curtis,[105] p. 224, table 3) = £435.76/week

LA, local authority.

a Source: Welsh National provider.

b Source: City and County of Swansea.

TABLE 65 Intervention unit costs and sources

Resource input	Unit costs (£)	Notes
Lay therapists[a]	15.94/hour	● Day support worker Scale Point 11–17 (£14,733–16,830)[b] ● Day service officer Scale Point 20–26 (£18,453–22,221)[b] ● Assistant manager Scale Point 29–31 (£24,646–26,276)[b] Balance of staff levels:[c] 15% lower, 70% middle and 15% higher Mean cost = £20,422 × 1.3 (on-cost) = £26,549, £15.94 per hour [converted using working hours/week = 37, weeks worked/year = 45 (Green Book[222])]
Supervising psychologist	46.69/hour	NHS Band 8c April 2010 = £54,454–67,134, mean = £59,799 × 1.3 (on-cost) = £77,739, £46.69 per hour [converted using working hours/week = 37, weeks worked/year = 45 (Green Book[222])]
Intervention psychologist	21.21/hour	NHS Band 7 (pt 26) to Band 8a (pt 34) April 2010 = £30,460–40,157, mean = £35,309, £21.21 per hour [converted using working hours/week = 37, weeks worked/year = 45, (Green Book[222])]
Administration	9.13/hour	NHS Band 2[d] April 2010 = £13,653–16,753, mean = £15,203, £9.13 per hour [converted using working hours/week = 37, weeks worked/year = 45 (Green Book[222])]
Telephone calls	0.06/minute	Assume 50% local @ £0.04 per minute[e] and 50% distant @ £0.08 per minute
Photocopying	0.04/page	£0.04 per A4 black and white page[f]

LA, local authority.

[a] We decided not to ask staff acting as lay therapists to disclose their salaries but rather to calculate a 'typical' cost based on established scales and scale mid-points, taking account the mix of seniority of staff actually delivering the intervention. We used LA day service staff costs to derive this, as this form of service delivery is the dominant form in the UK and our estimate of 'typical' delivery cost would therefore have maximum generalisation. However, it is likely that the estimate would not be significantly different had we factored in the mix of delivery settings: 50% of groups were run in LA day settings and a further 29% in voluntary sector settings (which have unit costs similar to LA day services). Moreover, wage rates for direct care staff and senior direct care staff do not differ greatly according to provision sector.

[b] Source: City and County of Swansea.

[c] Source: S Wales intervention centres.

[d] Source: www.nhscareers.nhs.uk; accessed 22 February 2012.

[e] Source: Cardiff University and BT. Mean = £0.06 per minute.

[f] Source: cheapest of three university rates: Birmingham, Cardiff and Glasgow.

BOX 3 Treatment as usual unit costs and sources

Revenue costs for LA day centre treatment as usual per service user hour in 2010 were £51 per session, which equates to £20.40/hour.[105] This figure includes a number of overheads that have not been accounted for in costing the intervention. Pages 16–17 of Curtis[105] contain the following estimates of such overheads: 'Total overheads (excluding travel and capital) as a percentage of direct salary costs have been estimated at 45 per cent of direct payroll with a range of 42 per cent to 56 per cent. Indirect overheads (cost of central functions such as finance, general management and human resources, including indirect running costs) were 16 per cent of direct salary costs (range of 1 to 20 per cent), direct overheads (administration and supervision) were 22 per cent of direct salary costs (range of 14 to 41 per cent) and premises (all office costs, uniforms, stationery etc.) were 7 per cent of direct salary costs (range of 2 to 9 per cent)'

Hence, the cost/hour of treatment as usual that is comparable to the intervention cost (i.e. exclusive of central functions, routine administration, supervision and premises costs) would be £20.40/1.45 = £14.07/hour

Appendix 3 Illustrative calculation

Illustrative calculation of how costs of staff were allocated to a participant living in staffed out-of-family accommodation

Calculations assume that morning, afternoon and evening are each 5 hours and the night 9 hours. Sleep-in night staff are costed at 0.33 × waking night-time cost. Staff costs per hour vary across types of setting (see *Appendix 2*).

The setting provides accommodation for seven people.

Typical staffing is two staff in the morning, two in the afternoon, two in the evening and one awake at night.

The total number of staff hours required to provide this staff cover is $(5 + 5 + 5) \times 2 + (1 \times 9) = 39$ staff hours per day.

This would cost $39 \times 7 \times$ £12.91/hour = £3524.43 per week.

The participant is reported to require less than half as much staff input than other people living in the accommodation (calculated as 33%).

There are six other people requiring three times the share of staff than the participant:

Three shares for six other people + one share for the participant means that the participant has 1/19 share of the staff $[1/[(6 \times 3) + 1]$.

The cost per week of staffing for the participant = £3524.43/19 = £185.50 per week.

Appendix 4 Psychotropic drug costs

Psychotropic drug costs (excluding anti-epilepsy drugs)

Prices are for one tablet per day at given dose for 1 week. The source costs are copied from the BNF (accessed December 2011 to February 2012). Anti-epilepsy drugs and a few non-psychotropic medications were also recorded. These have not been included in the analysis, as they would not be amenable to change as a result of the intervention.

Chlorpromazine	10 mg – £0.41/week
	20 mg – £0.82/week
	25 mg – £0.41/week
	100 mg – £0.46/week
	Tablets, chlorpromazine hydrochloride, 28-tab pack, net price: • 25 mg – £1.64 • 50 mg – £2.11 • 100 mg – £1.83
Citalopram	10 mg – £0.33/week
	20 mg – £0.92/week
	40 mg – £0.35/week
Seropram	Eight drops – £2.21/week
	Tablets, citalopram (as hydrobromide), 28-tab pack, net price: 10 mg – £1.31 20 mg – £3.37 40 mg – £1.39 *Oral drops*, citalopram (as hydrochloride), 40 mg ml^{-1}, net price: 15 ml – 11.85 [Note: Four drops (8 mg) is equivalent in therapeutic effect to 10-mg tablet]
Clonazepam	0.5 mg – £0.25/week
	Tablets, clonazepam, 100-tab pack, net price: 500 μg – £3.58 2 mg – £4.80
Depakote	250 mg – £0.95/week
	500 mg – £1.89/week
	750 mg – £2.84/week
	1230 mg – £4.73/week
	Tablets, e/c, valproic acid (as semisodium valproate), 90-tab pack, net price: 250 mg – £12.17 500 mg – £24.29

Diazepam	2 mg – £0.20/week
	4 mg – £0.40/week
	5 mg – £0.20/week
	10 mg – £0.21/week
	Tablets, diazepam, 28-tab pack, net price: 2 mg – £0.80 5 mg – £0.81 10 mg – £0.84
Fluoxetine	20 mg – £0.33/week
	40 mg – £0.66/week
	Capsules, fluoxetine (as hydrochloride), 30-cap pack, net price: 20 mg – £1.42 60 mg – £52.54
Haloperidol	5 mg – £0.53/week
	10 mg – £1.36/week
	15 mg – £1.89/week
	Tablets, haloperidol, 28-tab pack, net price: 500 μg – £0.91 1.5 mg – £1.29 5 mg – £2.09 10 mg – £5.42 20 mg – £13.92
Levomepromazine	50 mg – £3.38/week
	Tablets, scored, levomepromazine maleate, 84-tab pack, net price: 25 mg – £20.26
Lithium	600 mg – £0.40/week
	1000 mg – £0.77/week
Priadel	1400 mg – £0.86/week
	Tablets, m/r, both scored, lithium carbonate, 100-tab pack, net price: 200 mg (Li^+ 5.4 mmol) – £2.30 400 mg (Li^+ 10.8 mmol) – £3.35
Lorazepam	1 mg – £1.15/week
	2 mg – £2.30/week
	150 mg – assume 1.5 mg – £1.73/week
	Tablets, lorazepam, 28-tab pack, net price: 1 mg – £4.58 2.5 mg – £6.45
Mirtazapine	30 mg – £0.44/week
	45 mg – £0.84/week
	Tablets, mirtazapine, 28-tab pack, net price: 15 mg – £3.08 30 mg – £1.77 45 mg – £3.34

Olanzapine	5 mg – £10.95/week
	10 mg – £21.85/week
	15 mg – £29.80/week
	30 mg – £59.60/week
	Tablets, f/c, olanzapine, net price: 2.5 mg, 28-tab pack – £21.85 5 mg, 28-tab pack – £43.70 7.5 mg, 56-tab pack – £131.10 10 mg, 28-tab pack – £87.40 15 mg (blue), 28-tab pack – £119.18 20 mg (pink), 28-tab pack – £158.90
Paroxetine	20 mg – £0.53/week
	Tablets, paroxetine (as hydrochloride), 30-tab pack, net price: 20 mg – £2.25 30 mg – £2.69
Procyclidine	5 mg – £0.64/week
	20 mg – £2.56/week
	Tablets, procyclidine hydrochloride, 28-tab pack, net price: 5 mg – £2.56
Quetiapine	25 mg – £3.95/week
	300 mg – £19.83/week
	400 mg – £26.39/week
	500 mg – £33.03/week
	Tablets, f/c, quetiapine (as fumarate), 60-tab pack, net price: 25 mg (peach) – £33.83 100 mg (yellow) – £113.10 150 mg (pale yellow) – £113.10 200 mg (white) – £113.10 300 mg (white) – £170.00
Risperidone	1 mg – £0.18/week
	2 mg – £0.23/week
	5 mg – £0.62/week
	Tablets, risperidone, net price: 500 µg, 20-tab pack – £0.90 1 mg, 20-tab pack – £0.98; 60-tab pack – £1.58 2 mg, 60-tab pack – £1.94 3 mg, 60-tab pack – £2.43 4 mg, 60-tab pack – £3.75 6 mg, 28-tab pack – £26.11
Ritalin	10 mg – £1.30/week
	Tablets, scored, methylphenidate hydrochloride, 30-tab pack, net price: 10 mg – £5.57

Stellazine	17 mg – £1.61/week
	Tablets, both blue, f/c, trifluoperazine (as hydrochloride), net price: 1 mg, 112 – £4.11 5 mg, 112 – £5.87
Temazepam	0.5 mg – £0.49/week (costed on lowest price)
	Tablets, temazepam, 28-tab pack, net price: 10 mg – £2.77 20 mg – £1.97
Venlafaxine	75 mg – £0.47/week
	Tablets, venlafaxine (as hydrochloride), 56-tab pack, net price: 37.5 mg – £2.84 75 mg – £3.75
Zuclopenthixol	2 mg – £0.22/week
	Tablets, f/c, zuclopenthixol (as dihydrochloride), net price: 2 mg (red), 100 – £3.14 10 mg (light red-brown), 100 – £5.64 25 mg (red-brown), 100 – £7.22
Zuclopenthixol Decanoate	75 mg – £1.99/week
Weekly injection	200 mg – £1.99/week
Injection (oily), zuclopenthixol decanoate 200 mg ml^{-1}	Net price 1-ml amp – £1.99

e/c, enteric coated; f/c, film coated; m/r, modified release; tab, tablet.

Appendix 5 Regression models of pre–post analysis

Provocation Index pre–post multilevel regression analysis

Service user

Dependent variable is key worker-reported Provocation Index post intervention.

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	–42.1	0.160	–101.6	17.5
Service user PI pre intervention	0.6	< 0.001	0.5	0.8
Age of service user	–0.26	0.061	–0.5	0.0
Gender of service user (males vs females)	–5.1	0.080	–10.8	0.6
BPVS	0.0	0.650	–0.1	0.1
IQ	–0.1	0.713	–0.5	0.3
RSES pre intervention	0.1	0.780	–0.7	1.0
ComQoL pre intervention	0.0	0.410	–0.0	0.1
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs or less vs relevant degree or professional qualification)	4.1	0.637	–14.0	22.2
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels or HNC vs relevant degree or professional qualification)	2.5	0.681	–10.9	16.0
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs relevant degree or professional qualification)	3.7	0.660	–14.1	21.5
Gender of lay therapist (males vs females)	7.7	0.127	–2.5	18.0
Age of lay therapist	0.8	0.006	0.3	1.3
Region (Scotland vs Wales)	–2.4	0.701	–15.7	10.9
Region (England vs Wales)	–0.1	0.997	–17.2	17.2
Group size (fewer than four service users in a group vs more than six in a group)	3.1	0.648	–11.5	17.7
Group size (between four and six service users in a group vs more than six in a group)	6.4	0.255	–5.7	18.6
No. of sessions attended	–1.2	0.012	–2.1	–0.3
Group fidelity rating	0.5	0.016	0.1	0.9

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Key worker

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	20.2	0.396	–27.8	68.2
Key worker PI pre intervention	0.6	< 0.001	0.4	0.7
Age of service user	–0.2	0.086	–0.4	0.0
Gender of service user (males vs females)	–1.7	0.455	–6.1	2.8
BPVS	0.0	0.755	–0.1	0.1
WASIQ	–0.3	0.040	–0.7	–0.0
RSES pre intervention	–0.8	0.034	–1.5	–0.1
ComQoL pre intervention	0.0	0.237	–0.0	0.1
GDS pre intervention	0.8	0.004	0.3	1.3
GAS pre intervention	–0.2	0.082	–0.5	0.0
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs or less vs relevant degree or professional qualification)	10.5	0.192	–5.9	26.8
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels or HNC vs relevant degree or professional qualification)	6.9	0.299	–6.9	20.6
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs relevant degree or professional qualification)	8.5	0.335	–9.8	26.7
Gender of lay therapist (males vs females)	2.0	0.643	–7.2	11.3
No. of years lay therapist has worked in learning disability services	0.2	0.400	–0.04	0.9
Group size (fewer than four service users in a group vs more than six in a group)	–61,095.0	0.433	–227,342.000	105,153.000
Group size (between four and six service users in a group vs more than six in a group)	0.1	0.981	–11.7	12.0
Region (Scotland vs Wales)	7.4	0.247	–5.9	20.8
Region (England vs Wales)	3.3	0.686	–13.9	20.4
Group fidelity rating	0.3	0.155	–0.1	0.7

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Profile of Anger Coping Skills pre–post multilevel regression analysis

Service user

Dependent variable is self-reported PACS post intervention.

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	21.9	0.548	–51.0	94.7
PACS service user pre intervention	0.3	0.008	0.1	0.6
Age of service user	0.0	0.821	–0.3	0.4
Gender of service user (males vs females)	1.9	0.626	–5.9	9.7
BPVS	0.1	0.264	–0.1	0.2
WASIQ	–0.3	0.359	–0.8	0.3
RSES pre intervention	–0.5	0.413	–1.7	0.7
COMQOL pre intervention	0.1	0.269	–0.0	0.2
GDS pre intervention	0.8	0.072	–0.1	1.8
GAS pre intervention	–0.5	0.045	–1.0	–0.0
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs or less vs relevant degree or professional qualification)	–3.0	0.782	–25.4	19.4
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels or HNC vs Relevant degree or professional qualification)	–9.5	0.236	–26.5	7.5
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs Relevant degree or professional qualification)	–8.1	0.470	–32.2	16.0
Gender of lay therapist (males vs females)	13.3	0.044	0.4	26.1
Number of years lay therapist has worked in learning disability services	0.3	0.469	–0.5	1.1
Region (Scotland vs Wales)	–8.8	0.296	–26.3	8.8
Region (England vs Wales)	–17.2	0.111	–39.1	4.7
Group size (fewer than four service user in a group vs more than six in a group)	–3.5	0.710	–23.9	16.8
Group size (between four and six service user in a group vs more than six in a group)	3.1	0.643	–12.0	18.2
Number of sessions attended	1001.0	0.999	–1.3	1.3
Group fidelity rating	0.3	0.236	–0.2	0.8

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Key worker

Dependent variable is key worker-reported PACS post intervention.

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	50.7	0.123	–14.7	116.1
PACS key worker pre intervention	0.5	< 0.001	0.2	0.7
Age of service user	–0.1	0.324	–0.4	0.1
Gender of service user (males vs females)	2.5	0.366	–3.0	8.0
BPVS	–5783.0	0.899	–0.1	0.1
WASIQ	–0.1	0.498	–0.5	0.2
RSES pre intervention	0.4	0.396	–0.5	1.2
ComQoL pre intervention	–0.0	0.199	–0.1	0.0
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs, or less vs relevant degree or professional qualification)	–18.1	0.118	–41.4	5.2
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels, or HNC vs relevant degree or professional qualification)	–18.9	0.058	–38.6	0.8
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs relevant degree or professional qualification)	–22.7	0.084	–48.9	3.6
Gender of lay therapist (males vs females)	9.6	0.150	–4.0	23.1
No. of years lay therapist has worked in learning disability services	0.5	0.224	–0.4	1.4
Region (Scotland vs Wales)	–16.9	0.079	–36.0	2.3
Region (England vs Wales)	–13.9	0.242	–38.6	10.8
Group size (fewer than four support workers in a group vs more than six in a group)	4.8	0.676	–19.1	28.6
Group size (between four and six service users in a group vs more than six in a group)	9.9	0.233	–7.4	27.2
Group fidelity rating	–0.3	0.267	–0.9	0.3
No. of sessions attended	–0.2	0.590	–1.0	0.6

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Aberrant Behaviour Checklist pre–post multilevel regression analysis

Key worker

Dependent variable is key worker-reported ABC post-intervention.

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	26.8	0.143	–9.3	62.9
ABC pre intervention	0.8	< 0.001	0.6	0.9
Age of service user	–0.2	0.078	–0.3	0.0
Gender of service user (males vs females)	–3.5	0.094	–7.6	0.6
BPVS	0.0	0.604	–0.1	0.1
WASIQ	–0.2	0.232	–0.5	0.1
RSES pre intervention	–0.4	0.199	–1.1	0.2
ComQoL pre intervention	0.0	0.538	–0.0	0.1
GDS pre intervention	–0.3	0.101	–0.7	0.1
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs, or less vs relevant degree or professional qualification)	–4.8	0.412	–16.2	6.7
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels, or HNC vs relevant degree or professional qualification)	–3.5	0.354	–10.8	3.9
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs relevant degree or professional qualification)	1.2	0.815	–8.8	11.2
Gender of lay therapist (males vs females)	0.2	0.929	–4.3	4.7
Region (Scotland vs Wales)	2.1	0.570	–5.3	9.5
Region (England vs Wales)	3.3	0.503	–6.5	13.1
Group size (fewer than four service users in a group vs more than six in a group)	0.7	0.878	–8.0	9.3
Group size (between four and six service users in a group vs more than six in a group)	–2.7	0.359	–8.5	3.1
Group fidelity rating	0.1	0.477	–0.1	0.3
No. of sessions attended	0.0	0.953	–0.6	0.6

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Profile of Anger Coping Skills: imaginal provocation test pre–post ranked analysis of covariance analysis

Dependent variable is residuals from the regression of the ranked post PACS-IPT medians on the pre-PACS-IPT medians.

Variable	β	*p*-value	95% CI Lower bound	95% CI Upper bound
Intercept	0.9	0.045	0.0	1.7
Age of service user	2284.0	0.717	–0.0	0.0
Gender of service user (males vs females)	–0.3	0.080	–0.5	0.0
BPVS	–1031.0	0.629	–5254.0	3193.0
Lay therapist qualification (NVQ/SVQ level 2 or GCSEs or less vs relevant degree or professional qualification)	–0.1	0.642	–0.8	0.5
Lay therapist qualification (NVQ/SVQ level 3, Highers/A-levels or HNC vs relevant degree or professional qualification)	–0.4	0.017	–0.8	–0.1
Lay therapist qualification (NVQ/SVQ level 4, HND or irrelevant degree vs relevant degree or professional qualification)	–0.4	0.196	–0.9	0.2
Region (Scotland vs Wales)	–0.7	< 0.001	–1.1	–0.3
Region (England vs Wales)	–0.5	0.048	–0.9	–3616.0

Note: β is the regression coefficient and refers to the change in outcome per one unit change in covariate.

Appendix 6 Clinical psychologists' reflections

Reflections on the experience of providing training and supervision

All three clinical psychologists commented that providing supervision and training was one of the most enjoyable and positive aspects of their involvement in the study. The overall perception was that the training was generally appropriate and well received. Many of the concepts introduced within the training were entirely novel for the lay therapists, and clinical psychologists commented upon their apparent anxiety concerning their ability to engage the service users and respond appropriately to them in this context. However, they appeared to find the training, and the promise of further supervision around the group, reassuring. The psychologists commented on how encouraging it was to observe the lay therapists' development over the course of the group, and to hear accounts of the service users' progress. Hearing the lay therapists express their intentions to continue running groups subsequent to the conclusion of the study was particularly positive.

One clinical psychologist commented upon the positive impact of her involvement with the lay therapists upon the standing of clinical psychology in her local area. She perceived that providing day service staff with practical training and supervision allowed her to demonstrate how psychological approaches could be applied within their services, and how these skills could be useful to their own practice. She believed that some staff were somewhat wary of clinical psychologists, and perhaps felt that the psychologist was something of an intruder, whose role was to criticise their practice. She perceived an element of scepticism among some staff regarding the potential for psychological interventions to be effective. However, the experience of working collaboratively with staff to deliver an intervention had made her appear less of an 'outsider' to some of the day centre staff, and more of a 'useful resource'. She felt that this was likely to enhance working relationships in the future across a variety of joint tasks.

However, some of the psychologists' reflections did highlight the more difficult aspects of implementing the group intervention within the day services. Often, these were related to the disparity between service requirements and service provision. Each clinician considered the key role of service constraints upon their experience of providing training and supervision to the lay therapists. All acknowledged that the issue of staff availability was particularly salient to the ease with which the group intervention could be implemented. In services where staff shortages were in evidence, there were difficulties in arranging training and supervision, and group sessions were often cancelled.

There was a perception among the clinical psychologists that the lay therapists were offered very few opportunities to engage in training of this nature. This may, at least in part, explain the reported difficulties in some centres surrounding the selection of lay therapists. Two of the clinical psychologists specifically commented upon the politics of this aspect of implementation. In particular, it seemed that 'qualified' support staff questioned the appropriateness of involving those staff without formal qualifications in facilitating the group intervention. This seemed to reflect their perception that the role of lay therapist required skills that were usually associated with their 'qualified' status. However, it also seemed to reflect their desire not to miss out on an opportunity for training, when such opportunities were sparse.

Of course, such difficulties are often embedded within the political climate of particular services, and undoubtedly the groups did not operate apart from these contextual influences. Negotiating the relationships between staff members within services was a significant issue for at least one of the clinical psychologists. Indeed, this seemed symptomatic of other systemic difficulties within the service itself. The ethos in a minority of services did not appear particularly supportive of the group intervention, and in at least one service the lay therapists facilitating the group experienced hostility from their colleagues and disparaging comments regarding their efforts and the ongoing difficulties of some participants. Of course, this type of experience is particularly concerning because of the potential impact of such issues upon service users attending the centre.

In considering the actual process of supervision, it appeared that some of the lay therapists may have understood the term 'supervision' differently to the way in which it is typically used within clinical psychology. It seemed that some of the lay therapists had a relatively limited understanding of the supervision format, and indeed interpreted the term somewhat negatively, perhaps perceiving that the purpose of the supervision sessions was to enable the clinical psychologist to 'check up' on them. Other, perhaps more experienced or senior lay therapists, appeared to consider supervision a waste of their time. Thus, encouraging the lay therapists to use the supervision sessions for more reflective purposes was something of a developmental task over the course of each group. In some cases, using supervision for more reflective purposes was somewhat inhibited by difficulties in meeting the group of lay therapists together for supervision, a problem encountered by all three psychologists. Individual supervision sessions tended to yield different accounts of the group processes and progress, and without the opportunity to discuss these issues collaboratively, it was difficult to reach any consensus or resolution.

Interestingly, the clinical psychologists appeared to experience the supervision process somewhat differently. One found the therapists to be natural formulators, with an intuitive ability to engage in psychological thinking and little requirement for direction. Another commented that this appeared very difficult for the lay therapists in her area. The third found that these skills differed greatly from group to group, with some groups grasping the content of the sessions and working well to apply this appropriately to the needs of their own service users, and other groups requiring more guidance to consider how the material might be most usefully implemented.

Reflections on predicted outcomes

On the basis of these reflections, the clinical psychologists identified the following points as the rationale for their predictions of which groups would have the best and worst outcomes (see *Table 58*). As reported in *Chapter 9*, these predictions were confirmed with respect to the fidelity with which the intervention was delivered, and identified trends in the clinical outcomes.

What made groups more successful?

- Service users who were enthusiastic and engaged.
- Service users who were more cognitively able.
- Groups in which service users and staff were from a single service.
- Groups who developed a shared group identity and positive relationships.
- Groups that ran as scheduled.
- Lay therapists who had volunteered themselves, rather than been volunteered by their managers.
- Lay therapists who were prepared for the sessions and willing to take an active role.
- Lay therapists who could see the 'bigger picture' and could understand how the skills developed in the group could be used in everyday contexts, both for themselves and for the service users.
- Lay therapists who engaged with supervision and were reflective in their approach.
- Groups who were supported by thoughtful and committed day service managers.
- Groups being run within supportive services, with a positive attitude towards the potential for change.

What made groups less successful?

- Overstretched services.
- Groups that were largely unscheduled (ran according to availability of staff rather than according to a specific timetable).
- Groups in which service users had markedly varied levels of cognitive ability.
- Groups in which the lay therapists were selected because of simple availability or because of their own development needs, rather than because of their inherent suitability for the task.
- Groups involving individuals from more than one service.

EME
HS&DR
HTA
PGfAR
PHR

Part of the NIHR Journals Library
www.journalslibrary.nihr.ac.uk

Published by the NIHR Journals Library