

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

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Executive summary

CBT delivered by lay therapists to people with intellectual disabilities

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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.

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