The HELPER programme: HEalthy Living and Prevention of Early Relapse – three exploratory randomised controlled trials of phase-specific interventions in first-episode psychosis

Max Marshall, Christine Barrowclough, Richard Drake, Nusrat Husain, Fiona Lobban, Karina Lovell, Alison Wearden, Tim Bradshaw, Christine Day, Mike Fitzsimmons, Rebecca Pedley, Ruth Piccuci, Alicia Picken, Warren Larkin, Barbara Tomenson, Jeff Warburton and Lynsey Gregg
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Disclaimer: this report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

The HELPER programme: HEalthy Living and Prevention of Early Relapse – three exploratory randomised controlled trials of phase-specific interventions in first-episode psychosis

Max Marshall,1,2* Christine Barrowclough,2 Richard Drake,2 Nusrat Husain,1,2 Fiona Lobban,3 Karina Lovell,4 Alison Wearden,2 Tim Bradshaw,4 Christine Day,2,5 Mike Fitzsimmons,1,4 Rebecca Pedley,4 Ruth Piccuci,2,5 Alicia Picken,6 Warren Larkin,1 Barbara Tomenson,7 Jeff Warburton1 and Lynsey Gregg2

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Background: Schizophrenia represents a substantial cost to the NHS and society because it is common (lifetime prevalence around 0.5–1%); it begins in adolescence or early adulthood and often causes lifelong impairment. The first 3 years are a ‘critical period’ in which the course of the illness is determined. Hence under the NHS Plan, specialist early intervention in psychosis services were established to care for people who develop psychosis between the ages of 14 and 35 years for the first 3 years of their illness. However, there has been a lack of evidence-based treatments specifically designed for the early years. This is important because emerging evidence has shown that in the critical period it is vital to avoid relapse and prevent deterioration in physical health, as both can drastically reduce the chances of a full recovery.

Objectives: To develop and evaluate three phase-specific interventions to prevent relapse and/or deterioration in physical health in people with first-episode psychosis. The interventions were (1) cognitive remediation (CR) to improve meta-cognition and insight and enhance engagement in cognitive therapy [evaluated in the IMproving PArticipation in Cognitive Therapy (IMPACT) trial]; (2) a healthy-living intervention to control weight in people taking antipsychotic medication after a first episode of psychosis [evaluated in the INTERvention to Encourage ACTivity, Improve Diet, and Reduce Weight Gain (InterACT trial)]; and (3) integrated motivational interviewing and cognitive–behavioural therapy (MiCBT) to reduce cannabis use [evaluated in the Rethinking Choices After Psychosis (ReCAP) trial]. The trials were conducted to explore the case for larger definitive trials with relapse as a primary outcome measure. However, as small trials do not have sufficient power to detect significant reductions in relapse, each was focused on a relevant primary outcome for which there was sufficient power to detect a significant difference. In all three trials relapse was a secondary outcome in the hope of detecting trends towards lower relapse rates in the presence of effective interventions or a general trend across all three studies towards lower relapse rates.
Design: Three exploratory randomised controlled trials (RCTs) accompanied by qualitative work employing grounded theory and framework analysis to inform the interventions and determine acceptability (InterACT and ReCAP trials).


Participants: Early-intervention service users aged 16–35 years who had recently experienced a first episode of psychosis. Participants in the IMPACT trial were drawn from a waiting list of people referred for routine CBT; those in the InterACT trial were required to have a body mass index (BMI) of ≥ 25 kg/m² (or ≥ 24 kg/m² for service users from the South Asian community); and those in the ReCAP trial met Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV) criteria for cannabis abuse or dependence.

Interventions: The IMPACT trial involved 13 sessions of CR over 12 weeks; the InterACT trial involved eight face-to-face sessions plus optional group activities over 12 months; and the ReCAP trial involved MiCBT in brief (12 sessions over 4.5 months) and long (24 sessions over 9 months) forms.

Main outcome measures: The primary outcome in the IMPACT trial was psychotic symptoms assessed by the Psychotic Symptom Rating Scales (PSYRATS). BMI was the primary outcome in the InterACT trial and cannabis use (measured by timeline follow-back) was the primary outcome in the ReCAP trial. Relapse was a secondary outcome across all three trials.

Results: In the IMPACT trial there was no beneficial effect of CR on psychotic symptoms; however, the amount of CBT required was significantly less after CR. In the InterACT trial a small reduction in BMI in the intervention group was not statistically significant. For participants taking olanzapine or clozapine the effect size was larger although not significant. Outcome data from the ReCAP trial are not yet available. Retention in all three trials was good, indicating that the interventions were acceptable.

Conclusions: Early-intervention services provided a good setting to conduct trials. The IMPACT trial found that CR delivered by relatively unskilled workers improved the efficiency of subsequent CBT. Across the three trials there was little evidence that any intervention reduced relapse.

Trial registration: Current Controlled Trials ISRCTN17160673 (IMPACT); Current Controlled Trials ISRCTN22581937 (InterACT); Current Controlled Trials ISRCTN88275061 (ReCAP).

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Results
Discussion
Qualitative acceptability interviews
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<td>Asking about Substance use and Psychosis – Ideas, Reactions and Experiences</td>
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<td>BABCP</td>
<td>British Association for Behavioural and Cognitive Psychotherapies</td>
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<tr>
<td>BAI</td>
<td>Beck Anxiety Inventory</td>
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<tr>
<td>BARS</td>
<td>Brief Adherence Rating Scale</td>
</tr>
<tr>
<td>BMI</td>
<td>body mass index</td>
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<tr>
<td>CBT</td>
<td>cognitive–behavioural therapy</td>
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<tr>
<td>CBTp</td>
<td>cognitive–behavioural therapy for psychosis</td>
</tr>
<tr>
<td>CDSS</td>
<td>Calgary Depression Scale for Schizophrenia</td>
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<tr>
<td>CENTRAL</td>
<td>Cochrane Central Register of Controlled Trials</td>
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<tr>
<td>CI</td>
<td>confidence interval</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<td>CR</td>
<td>cognitive remediation</td>
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<tr>
<td>CSM</td>
<td>common-sense model</td>
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<tr>
<td>CTSpsy</td>
<td>Cognitive Therapy Scale for Psychosis</td>
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<tr>
<td>DAI</td>
<td>Drug Attitude Inventory</td>
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<tr>
<td>DSM-IV</td>
<td><em>Diagnostic and Statistical Manual of Mental Disorders</em> – Fourth Edition</td>
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<tr>
<td>DUP</td>
<td>duration of untreated psychosis</td>
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<td>EIS</td>
<td>early-intervention service</td>
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<td>EQ-5D</td>
<td>European Quality of Life-5 Dimensions</td>
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<tr>
<td>GAF</td>
<td>Global Assessment of Functioning</td>
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<td>HELPER</td>
<td>HEalthy Living and Prevention of Early Relapse</td>
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<td>HR</td>
<td>hazard ratio</td>
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<td>ICD-10</td>
<td><em>International Classification of Diseases</em>, 10th revision</td>
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<td>IMPACT</td>
<td>IMproving PArticipation in Cognitive Therapy</td>
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<td>InterACT</td>
<td>INTERvention to Encourage ACTivity, Improve Diet and Reduce Weight Gain</td>
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<td>IPAQ</td>
<td>International Physical Activity Questionnaire</td>
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<td>IQ</td>
<td>intelligence quotient</td>
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<td>IQR</td>
<td>interquartile range</td>
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<td>IS</td>
<td>Insight Scale</td>
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<td>mental component summary</td>
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<td>MET</td>
<td>metabolic equivalent</td>
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<td>MI</td>
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<td>MiCBT</td>
<td>integrated motivational interviewing and cognitive–behavioural therapy</td>
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<td>Motivational Interventions for Drugs and Alcohol misuse in Schizophrenia</td>
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<td>MITI</td>
<td>Motivational Interviewing Treatment Integrity</td>
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<td>MRC</td>
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<td>NICE</td>
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<td>openCDMS</td>
<td>Open Source Clinical Data Management System</td>
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<td>OR</td>
<td>odds ratio</td>
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<td>Positive and Negative Syndrome Scale</td>
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<td>Psychotic Symptom Rating Scales</td>
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<td>RCT</td>
<td>randomised controlled trial</td>
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<td>ReCAP</td>
<td>Rethinking Choices After Psychosis</td>
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<td>RTCQ</td>
<td>Readiness to Change Questionnaire</td>
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<td>SCID</td>
<td>Structured Clinical Interview for DSM-IV Axis 1 Disorders</td>
<td>STR</td>
<td>support, time and recovery worker</td>
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<td>SD</td>
<td>standard deviation</td>
<td>TAU</td>
<td>treatment as usual</td>
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<td>SF-36</td>
<td>Short Form questionnaire-36 items</td>
<td>TLFB</td>
<td>timeline follow-back</td>
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<tr>
<td>SMD</td>
<td>standardised mean difference</td>
<td>WAIS</td>
<td>Wechsler Adult Intelligence Scale</td>
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<tr>
<td>SMR</td>
<td>standardised mortality ratio</td>
<td>WCST</td>
<td>Wisconsin Card Sort Task</td>
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<td>SOFAS</td>
<td>Social and Occupational Functioning Assessment Scale</td>
<td>WTAR</td>
<td>Wechsler Test of Adult Reading</td>
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Plain English summary

Background

Psychosis means:

- hearing or seeing things that are not there
- believing things that cannot be true and
- having confused thoughts.

Schizophrenia is a type of psychosis. After an attack of psychosis people can find it hard to get back to normal. People get worse after each attack.

Aims

We wanted to stop people having another attack of psychosis. We looked at three treatments. The first was a ‘mind gym’, similar to a computer game. We hoped that it would make talking therapies work better. The second helped people control their weight by healthy living. Drugs for psychosis make you gain weight and so people stop taking them. The third was a talking therapy designed to help users give up cannabis. Cannabis use causes further attacks of psychosis. We carried out a small trial for each of our treatments. We wanted to see if any were promising enough for us to carry out a much bigger study.

Methods

Our first trial (mind gym) involved 61 people waiting for talking therapy (cognitive–behavioural therapy) after their first attack of psychosis. Our second trial (weight control) involved 105 people. Our third trial (stopping cannabis) involved 110 people.

Results

People liked all three treatments. The mind-gym treatment made talking therapy work more quickly. The healthy-living treatment did not work that well although it might have helped some people who take drugs that cause a lot of weight gain. So far we do not know how well the stopping-cannabis treatment worked.

Conclusions

The mind gym is worth testing in a bigger trial.
Scientific summary

Background

Schizophrenia represents a substantial cost to the NHS and society because it is common (lifetime prevalence around 0.5–1%); it begins in adolescence or early adulthood and often causes lifelong impairment. The first 3 years are a ‘critical period’ in which the course of the illness is determined. Hence, under the NHS Plan, specialist early intervention in psychosis services were established to care for people who develop psychosis between the ages of 14 and 35 years for the first 3 years of their illness. However, there has been a lack of evidence-based treatments specifically designed for the early years. This is important because emerging evidence has shown that in the critical period it is vital to avoid relapse and prevent deterioration in physical health, as both can drastically reduce the chances of a full recovery.

It is important to avoid relapse after the first episode because with each successive relapse the illness becomes more difficult to treat; the number of individuals who achieve a full recovery declines; and the level of residual disability mounts. Those who relapse are more likely to have poor outcomes such as treatment resistance, suicide and causing harm to others. Studies from the UK and abroad have shown that our success in preventing relapse is poor. Although 85% of people who develop psychosis recover fully from the first episode, 48–51% may relapse within 18 months, even within early-psychosis teams. Over a 5-year follow-up as many as 80% may relapse.

One way to avoid relapse is to make psychological treatments more effective. An evaluation of cognitive remediation (CR) in combination with cognitive–behavioural therapy (CBT) was included in this study, as CR targets neuropsychological deficits that predispose to poor insight and hamper participation with therapy. CR was evaluated in people on the waiting list for cognitive therapy to see whether or not prior receipt of CR improved their meta-cognition and insight, enhanced their subsequent engagement in cognitive therapy and ultimately reduced relapse.

Antipsychotic medication is a key way of preventing relapse but unfortunately it can contribute to poor health. Physical inactivity and poor diet are more common in people with schizophrenia than in the general population and antipsychotic medication amplifies the effect of these risk factors. In the UK in the 1990s the standardised mortality ratio (SMR) for death from natural causes was 232 [95% confidence interval (CI) 172 to 600] for people with schizophrenia. The SMR was 468 for avoidable causes, 187 for cardiovascular disease, 534 for cerebrovascular disease and 996 for diabetes mellitus. This high level of mortality is a result of lack of physical activity, smoking and reduced access to preventative treatments. These SMRs have since increased, with much of the increase attributable to deaths from natural causes, especially circulatory disease and respiratory disease. As Saha et al. state, ‘in light of the potential for second-generation antipsychotic medications to further adversely influence mortality rates . . . optimising the general health of people with schizophrenia warrants urgent attention’ (Saha S, Chant D, McGrath J. A systematic review of mortality in schizophrenia: is the differential mortality gap worsening over time? Arch Gen Psychiatry 2007;64:1123–31). Intervention in the critical period is the key to preventing this excess mortality because this is when (1) most antipsychotic medication-induced weight gain occurs; (2) diabetes mellitus develops; and (3) unhealthy behaviours such as inactivity and substance misuse become deeply ingrained. Our systematic reviews of treatments in early-psychosis and healthy-living interventions in schizophrenia have shown that there are no established phase-specific interventions for preventing relapse or deterioration in health, and we therefore developed a healthy-living intervention aimed at reducing weight. We expected that if people felt healthier they might have lower rates of relapse.

We also targeted substance use, in particular cannabis use, as it predicts relapse in first-episode patients and because rates of substance use in first-episode psychosis are high.
Objectives

The overarching aim of the HEalthy Living and Prevention of Early Relapse (HELPER) programme was to develop three linked phase-specific interventions to prevent relapse of psychosis and/or deterioration in physical health in people who have experienced a first episode of psychosis. The interventions, linked by a common theoretical framework (the self-regulatory model of illness management), were designed for optimum delivery by the national network of early-intervention service teams. The main objectives of the programme were to:

1. evaluate CR to improve meta-cognition and insight and enhance engagement in cognitive therapy [the IMproving PArticipation in Cognitive Therapy (IMPACT) trial]
2. develop and evaluate a healthy-living intervention to control weight in people taking antipsychotic medication after a first episode of psychosis [the INTERvention to Encourage ACTivity, Improve Diet, and Reduce Weight Gain (InterACT trial)]
3. optimise and evaluate motivational interviewing (MI) and CBT for substance misuse [the Asking about Substance use and Psychosis – Ideas, Reactions and Experiences (ASPIRE) and Rethinking Choices After Psychosis (ReCAP) trials]
4. identify any trends towards lower relapse rates within and across trials (IMPACT, InterACT and ReCAP trials).

The trials were exploratory in nature and designed to make the case (or otherwise) for larger definitive trials with relapse as a primary outcome measure. However, as small exploratory trials do not have sufficient power to detect clinically significant reductions in relapse, each trial was focused on a relevant primary outcome for which there was sufficient power to detect a clinically significant difference. In all three trials relapse was a secondary outcome, with the aim of detecting trends towards lower relapse rates in the presence of effective interventions or a general trend across all three studies towards lower relapse rates.

Methods

The three interventions included in the programme are complex and were evaluated in line with the Medical Research Council (MRC) framework for the development and evaluation of complex interventions. The two interventions that were optimised for the programme were informed by preliminary qualitative work using grounded theory and framework analysis to ensure that the illness models of the intended participants were taken into account in the adaptation (as specified by the self-regulatory model). The three trials evaluating the interventions were all methodologically robust single-blind randomised controlled trials: two exploratory and one pragmatic. The IMPACT trial involved 61 patients who were on the waiting list for cognitive therapy, with 31 randomised to receive CR and 30 randomised to receive social contact. In the InterACT trial, 105 participants consented to take part: 54 were randomised to the healthy-living group and 51 were randomised to the treatment-as-usual (TAU) group. In the ReCAP trial 110 participants were randomised to brief therapy (n = 38), longer duration therapy (n = 37) or TAU (n = 35).

Results

Engagement and retention rates in all three trials were good, indicating that the interventions were feasible to deliver and acceptable to participants. Our hypotheses concerning the impact of the interventions on outcome were partially supported. In the IMPACT trial, CR was not associated with significantly lower Psychotic Symptom Rating Scales (PSYRATS) scores over the period of study (p = 0.39) but was associated with better insight (p = 0.02). CR improved the efficiency of CBT (p = 0.011); after CR, participants made the same amount of progress in half the number of CBT sessions. Global cognition did not improve significantly more after CR (p = 0.20) but executive function did (Wisconsin Card Sort Task; p = 0.012). In the InterACT trial the healthy-living intervention was associated with a small reduction in body mass index (BMI) in the intervention group but not in the TAU group, but the effect size was
small (0.11) and the difference not statistically significant ($p = 0.44$). There was evidence to suggest that the intervention may be more effective in participants taking olanzapine and clozapine (effect size 0.55 for weight loss, 0.54 for BMI reduction); although, again, these differences were not statistically significant ($p = 0.19$ and 0.20 respectively). Health and social care costs were lower in the TAU group but the difference was not statistically significant ($p = 0.69$) and relapse rates were similar. However, full cost data were not available for all participants who completed follow-up and further analysis is planned. In the ReCAP trial, integrated motivational interviewing and cognitive–behavioural therapy (MiCBT) was accepted by the majority of people to whom it was offered (80%), indicating that the intervention was acceptable to participants. The median number of therapy sessions attended in both of the therapy arms was similar, indicating that a brief form of the intervention may be more acceptable than a longer form. There was no difference in relapse rates between the three arms.

Conclusions

Early-intervention services provided a good setting to conduct trials of phase-specific interventions, and good rates of recruitment and retention were achieved across all three trials.

The IMPACT trial showed that CR delivered by relatively unskilled workers can improve the efficiency of subsequent CBT, enabling participants and therapists to achieve the same amount of progress in therapy in approximately half the number of sessions. A substantial increase in the efficiency of CBT implies that the same number of CBT therapists could treat many more patients.

The InterACT trial showed that we were able to train support, time and recovery workers to deliver a healthy-living intervention but that the effect of the intervention on weight reduction or controlling weight gain was small and not statistically significant. The effect of the intervention was larger in the subgroup taking olanzapine and clozapine, suggesting that future work should focus attention on this subgroup of service users.

The ReCAP trial showed that the MiCBT intervention was acceptable to young cannabis users in early psychosis, but it is not yet known whether or not MiCBT improved outcome in terms of reducing cannabis use or improving clinical outcome. The results, when available, will be a significant addition to the evidence base and will be of considerable interest to academics and clinicians in the field.

Recommendations for future research

In order of priority:

1. The IMPACT trial may have shown that CR had a positive impact on the efficiency of CBT. We therefore recommend that a definitive trial of CR-aided CBT should be conducted with improvement in the efficiency of CBT as the primary outcome measure.

2. The InterACT trial showed that a healthy-living intervention might possibly work better for people who are taking olanzapine or clozapine. Further work should, therefore, be carried out to improve the effectiveness of the healthy-living intervention, particularly with a focus on those who are taking olanzapine or clozapine.

3. We found that early-intervention services provided a good setting for carrying out research because they support retention and recruitment and there is strong engagement from service users and staff. Consideration should be given to setting up a national programme of phase-specific research within early-intervention services.
Trial registration

The IMPACT trial is registered as ISRCTN17160673, the InterACT trial is registered as ISRCTN22581937 and the ReCAP trial is registered as ISRCTN88275061.

Funding

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.
Chapter 1 Cognitive remediation workstream: IMproving PArticipation in Cognitive Therapy (IMPACT) – a randomised controlled trial

Abstract

Background: Schizophrenia can be an intractable illness and so it is important to understand how far combining therapies creates synergy. Cognitive remediation (CR), which improves neuropsychological deficits, might combine well with cognitive–behavioural therapy (CBT), which improves symptoms.

Hypothesis: Following a first episode of non-affective psychosis, CR will enhance the efficacy and efficiency of subsequent CBT.

Methods: Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition (DSM-IV) non-affective psychosis patients aged 18–35 years who were on waiting lists for routine CBT from NHS early-intervention services were randomised to receive either computerised CR over 12 weeks supported by a trained support worker or time-matched social contact (SC). All then received 6–30 weeks of CBT. The primary outcome was the Psychotic Symptom Rating Scales, blind-rated at baseline, after remediation (12 weeks) and after CBT (42 and 54 weeks). Secondary outcomes included duration of CBT, cognition, insight, other symptoms, relapse and self-esteem.

Results: There was no significant difference in psychotic symptoms between the remediation group and the comparison group (coefficient 0.3, 95% confidence interval (CI) –0.4 to 1.1; \( p = 0.39 \)). However, duration of CBT was shorter after remediation [median seven sessions, interquartile range (IQR) 2–12 sessions] than after SC (median 13 sessions, IQR 4–18 sessions; \( p = 0.011 \)) and linked to better insight (\( p = 0.02 \)). Global cognition did not improve significantly more after remediation (\( p = 0.20 \)) but executive function did (Wisconsin Card Sort Task; \( p = 0.012 \)). No other outcomes differed significantly.

Discussion: The duration of CBT after CR was substantially shorter than after an active control, perhaps mediated by improved neuropsychological function. Remediation was delivered by staff with minimal training and thus CR might considerably reduce the costs of CBT.

Introduction

Combination therapy has proven fruitful in many difficult-to-treat conditions. It has been widely touted as a means of targeting otherwise intractable symptomatic, social and cognitive outcomes of schizophrenia.1–3 However, studies of combination therapy (especially of non-pharmacological interventions) are complex, expensive and difficult to organise. Typically, such trials have studied multiple interventions embedded within new service designs4–7 or complex programmes of care5–8 Although these studies have shown promising findings, the therapeutic offering is often so complex that it is difficult to extract precise information about the synergistic benefits, or otherwise, of combining specific interventions.2 Studies of specific combinations of interventions are often open trials4–7,9–16 or have incompletely matched control conditions.9–16 Hence there is a pressing need for further work in this area.
Cognitive remediation (CR) and cognitive–behavioural therapy for psychosis (CBTp) are good candidates for combination therapy in early schizophrenia for four reasons. First, both interventions have efficacy,\textsuperscript{1,16–18} even in the early stages of schizophrenia.\textsuperscript{11,19} Systematic reviews show that CR improves cognitive measures across a range of domains,\textsuperscript{16} with effect sizes ranging from 0.15 to 0.65, whereas CBTp improves overall symptoms, with an effect size of 0.40 (95% CI 0.25 to 0.55).\textsuperscript{17} Second, each intervention targets different but complementary aspects of the condition. Third, combining CR and CBTp makes sense in terms of service delivery, as the time spent waiting for CBTp from a specialist is a window of opportunity for computer-aided CR delivered by generic staff. Fourth, cognitive impairment is an obstacle to participation in CBTp, for example deficits in verbal memory (logical memory test) predict reduced CBTp efficacy.\textsuperscript{20} It seems logical to offer CR to people with early psychosis before they have CBTp, as improved cognitive and social functioning arising from CR should lead to improved engagement with CBTp and ultimately to better outcomes.

In the NHS, early-intervention services look after all young adults with a first episode of psychosis and we therefore had a unique opportunity to examine the impact of CR combined with CBT in those who had suffered a recent first episode. This group is relatively unselected, as even those who will have a relatively good illness course are represented. It is also less socially and cognitively impaired and, being young and early in the illness career, perhaps neurophysiologically more plastic. Early-intervention services are expected to offer CBTp as part of their programme of care.\textsuperscript{1,21} We planned a naturalistic trial, randomising service users to 12 weeks of CR or to a parallel time-matched SC control group, with both groups going on to receive CBTp from early-intervention services as part of usual care. CBTp offered in this way would usually last from 6 to 30 weeks, as determined by therapeutic need.

Our primary hypothesis was that CR would enhance the efficacy of CBTp, with symptoms reducing faster and further during CBTp preceded by CR. A secondary hypothesis was that CR would enhance the efficiency of CBTp, facilitating shorter courses or greater progress.

**Methods**

**Participants**

We identified potential participants among outpatients on waiting lists for CBTp from Lancashire Care NHS Foundation Trust’s and Pennine Care NHS Foundation Trust’s early-intervention services. Inclusion criteria were age 18–35 years and first episode of DSM-IV\textsuperscript{22} schizophreniform disorder, schizophrenia, schizoaffective disorder or delusional disorder, confirmed by semistructured interview.\textsuperscript{23} Exclusion criteria were International Classification of Diseases, Tenth Edition (ICD-10)\textsuperscript{24} organic brain disease; DSM-IV substance abuse or dependence; primary diagnosis of DSM-IV substance-induced psychosis; and insufficient fluency in English to participate in neuropsychological assessment. All participants provided written informed consent and the study was approved by the Bolton NHS Local Research Ethics Committee (reference 08/H1009/76) and was consistent with the UK Research Governance Framework for Health and Social Care.\textsuperscript{25}

**Outcome assessments**

At baseline, demographic details (including self-ascribed ethnicity as a potential moderator of CR and CBTp outcome) and medication were recorded. The PSYRATS (Psychotic Symptom Rating Scales\textsuperscript{26}) were the primary outcome measure, completed with other measures at baseline and after 12 and 42 weeks’ follow-up (Figure 1). The PSYRATS validly and reliably assess the severity of delusions and hallucinations in first-episode schizophrenia.\textsuperscript{27} Intraclass correlation coefficients between assessors were > 0.99 for subtotals and the total score.
Assessments at baseline and 12 and 42 weeks included secondary measures of symptoms and function: the Positive and Negative Syndrome Scale (PANSS), the Calgary Depression Scale for Schizophrenia (CDSS), the Rosenberg Self-Esteem Scale and the Social and Occupational Functioning Assessment Scale (SOFAS). A seven-item version of the Insight Scale (IS), with the hospitalisation item dropped for this community sample, was scored from 0 to 14.

The PSYRATS were also rated at 6-week intervals during the CBT envelope, at 12–42 weeks. Participants completed these interviews in person, or by telephone if they preferred. As CBT was sometimes delayed or prolonged, and therefore incomplete by 42 weeks, the PSYRATS were also completed by telephone or in person at 54 weeks.

Cognitive–behavioural therapy for psychosis typically aims to progress from engagement, through examination of the nature of individual problems, to integration of problems into a formulation describing origins, schemata and maintaining mechanisms. At the end of CBT, therapists assessed this progression using a five-point score.
An assessor blind to allocation extracted the number of sessions of CBTp from case records and identified readmission and relapse (defined, as elsewhere,34 as an exacerbation of psychotic symptoms lasting at least 2 weeks, leading to a change in management).

**Neuropsychological assessments**

Intelligence quotient (IQ) was assessed at baseline with the Wechsler Adult Intelligence Scale (WAIS) block design subtest and the Wechsler Test of Adult Reading (WTAR).35 Secondary neuropsychological assessments of attention, executive function and memory were completed at baseline and at 12 and 42 weeks using the Wisconsin Card Sort Task (WCST),36 trail making,37 the 0-back version of the n-back task,38 paragraph recall39,40 and the Rey–Osterrieth Complex Figure Test41 (Table 1 contains details and rationales).

**Allocation**

Within 3 days of initial assessment assessors faxed details of participants to identified administrators who were independent of the trial team and unaware of the hypothesis. They used randomly permuted variable blocks53 to allocate participants to the experimental group or the comparison group, masked from assessors, and then communicated allocation by telephone to the researchers providing the study interventions, before faxing them participants’ details.

**Interventions**

Cognitive remediation was provided in patients’ homes or service bases using the CIRCUITS software, (Reeder and Wykes, Institute of Psychiatry, Psychology and Neuroscience, King’s College London, UK)54 run from a secure website via the internet or on a DVD. Based on a CR programme validated in schizophrenia patients,42,55 it used a colourful, engaging, virtual town as an environment, guiding participants through a sequence of tasks. This provided a social context for tasks, each requiring a specific mixture of skills (e.g. sustained attention, working memory, registration and recall, planning) and with specific criteria for progression. Early tasks prepared for later ones of increasing difficulty and complexity. Trainers supported participants and could enter their virtual environment with privileges that allowed them to modify the sequence.

Trainers were psychology graduates who had undergone 1 week of specific training (a regular open course provided by Clare Reeder and Til Wykes) to deliver CIRCUITS. CIRCUITS is based on well-established CR principles (Table 2).

**TABLE 1 Neuropsychological assessments and their rationales**

<table>
<thead>
<tr>
<th>Task</th>
<th>Neuropsychological rationale</th>
<th>Significance in previous CR trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computerised, meta-cognitive version of the Wisconsin Card Sort Task (MC-WCST)</td>
<td>Categories complete measures schema formation</td>
<td>Predicted a range of psychosocial outcomes43-45</td>
</tr>
<tr>
<td></td>
<td>Free choice improvement measures meta-cognitive skill</td>
<td></td>
</tr>
<tr>
<td>Trail making A</td>
<td>Vigilance and motor speed</td>
<td>Predicted psychosocial outcome43,44</td>
</tr>
<tr>
<td>Trail making B</td>
<td>Set alternation and working memory</td>
<td>Predicted psychosocial outcome43,44</td>
</tr>
<tr>
<td>0-back version of the n-back task</td>
<td>Basic CPT</td>
<td>CPT predicted psychosocial outcomes43,44,45</td>
</tr>
<tr>
<td>Immediate and 30-minute paragraph recall</td>
<td>Memory skills related to structured narrative,40,41 expected to be important in CBTp</td>
<td>Predicted social skills improvement; predicted social function outcomes of linked rehabilitation programmes41,49,52</td>
</tr>
<tr>
<td>Rey–Osterrieth Complex Figure Test</td>
<td>Accuracy of copying: visual–spatial function 30-minute recall: visual memory</td>
<td>Comparison with structured verbal immediate and delayed recall</td>
</tr>
</tbody>
</table>

CPT, continuous performance test.
The comparison condition was SC with support workers, with the duration of exposure matching that of exposure to the CR trainers. Both conditions provided interpersonal contact, warmth and unconditional positive regard within a professional relationship. Social activity (conversation, neurocognitively undemanding recreations) was the basis of sessions, although when necessary workers supported participants sufficiently to maintain their motivation to attend (i.e. non-directive listening concerning problems and symptoms).

Cognitive–behavioural therapy for psychosis was provided separately by therapists employed specifically for that purpose by the two NHS services who worked in seven different community clinics. All had specific CBTp training and were supervised by experienced senior CBTp therapists according to National Institute for Health and Care Excellence (NICE) standards. CBTp quality was assessed using the Cognitive Therapy Scale for Psychosis (CTSpsy), independently rated from randomly selected audio-taped sessions, provided that therapists thought it clinically appropriate and patients provided separate written consent. The mean CTSpsy score for seven CBTp interviews was 75.2% (standard deviation (SD) 14.5%).

**Analysis**

The effect of group on PSYRATS score was estimated using a mixed-effects model estimated using full information maximum likelihood with Stata version 11.2 (StataCorp LP, College Station, TX, USA). Allocation group and a group × time interaction term modelled the intervention’s effect. Time was entered as the square root of weeks from baseline; as PSYRATS scores tended to level off during follow-up this improved the model fit. Demographic and other baseline potential confounders (lack of antipsychotic prescription, previous illicit substance use, diagnosis of schizophrenia) were removed by backward elimination, the criterion for retention being

\[ p < 0.20. \]

PANSS, SOFAS and depression and self-esteem scales were analysed in the same way. Insight, in its mixed-effects model, was transformed towards normality by squaring the Insight Scale (IS) score. Insight changed relatively linearly over time and so weeks from baseline was entered as the time variable. A logistic regression against dropout with baseline variables as predictors assessed the pattern of missing data in relation to these variables.

As a categorical outcome, remission was defined as a PSYRATS score of zero. The relative risk of remission after CR was calculated and used to derive the number needed to treat/harm.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Procedure</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of meta-cognitive (i.e. ‘thinking about thinking’) regulation and knowledge</td>
<td>Therapists’ and CIRCUITS prompts encourage participants to reflect on, learn about and develop strategies to systematically regulate their thinking and behaviour</td>
<td>Facilitates the transfer of new cognitive skills to a wide variety of situations within everyday life</td>
</tr>
<tr>
<td>Focus on transfer</td>
<td>Participants encouraged to define and work towards recovery-related goals and to consider how within-therapy cognitive skills can help improve everyday living skills</td>
<td>Aims to promote motivation and improved social functioning</td>
</tr>
<tr>
<td>Errorless learning</td>
<td>Therapists modulated difficulty to prevent repeated errors and participants progressed to harder tasks only once they were responding correctly</td>
<td>Prevents repeated errors that impair learning</td>
</tr>
<tr>
<td>Scaffolding</td>
<td>Trainers and the CIRCUITS tasks themselves initially provided strategies to support participants, but as difficulty increased this support was reduced</td>
<td>Forces participants to develop their capacity to strategize</td>
</tr>
<tr>
<td>Massed practice (frequent rehearsal)</td>
<td>Participants allowed to complete tasks between their sessions with trainers, with assignments reviewed at the start of sessions</td>
<td>Aiming for three to five 1-hour sessions per week and 40 hours’ intervention in 12 weeks</td>
</tr>
</tbody>
</table>
For neuropsychological measures, a global score was calculated. Individual baseline scores were transformed to normal distributions with a mean of 100 and SD of 15, with higher scores indicating better performance, before deriving a global score with the same characteristics. The same transformations were applied to 12- and 42-week follow-up scores, giving distributions with various means and SDs. The global score was then entered into a mixed-effects model.

In this relatively able population, WCST categories complete and complex figure copying (rather than recall; see Table 1) scores were too skewed by ceiling effects for this process. Categories complete and copying were modelled by ordinal logistic regression against follow-up scores, adjusting for baseline scores and potential confounders after backward elimination, clustering by clinic. To examine the sensitivity of ordinal logistic and linear regressions to the effect of dropout, all were repeated with cases probability weighted by a function of the risk of attrition, derived from the logistic regression against dropout. That is, the number of each case \(n=1\) was multiplied by the reciprocal of the risk of completion of that type of case (calculated from a logistic regression using baseline characteristics to predict which cases would finish the study), so that cases of a type who more often dropped out appeared to be more frequent (e.g. apparent or weighted \(n=1.43\) if the probability of completion for a case with those demographic and clinical baseline characteristics was 0.7) to make up for the cases who did, in fact, drop out.

Time to relapse and readmission for allocation groups were compared by log-rank tests. Cox regressions adjusted hazard ratios (HRs) for potential demographic and clinical confounders, stratified by clinic.

**Sample size**
Assuming (after the trial by Eack and colleagues\(^1\)) a PSYRATS effect size of 0.5, recruiting 64 participants provides >80% power with a two-tailed alpha of 0.05, correlation of 0.5 between seven successive assessments and 25% dropout.

**Results**

**Experimental and comparison group characteristics**
In total, 272 CBTp waiting list patients were screened for eligibility (Figure 2). Of these, 66 consented to participate, of whom four withdrew, leaving 62 to be randomised. One was subsequently excluded as a concealed history of previous psychosis rendered him ineligible and so 61 entered a modified intention-to-treat analysis (Table 3). Seven in the CR group and four in the SC group did not take maintenance antipsychotics \(p=0.51\), Fisher’s exact test). No anticholinergics were prescribed and only one in each group took medication with high muscarinic receptor affinity (clozapine). Assessors accidentally discovered two participants’ allocation group during the trial, one from each group. CBTp therapists discovered eight participants’ allocation group (five CR group and three SC group) but their guesses at the allocation of the other participants were no better than chance \(p=0.43\), Fisher’s exact test). Logistic regression against completion found no significant predictors of dropout.

There was no significant difference in exposure to CR trainers/exposure to support workers between the two groups (SC: median 390 minutes, IQR 145–610 minutes, CR: median 375 minutes, IQR 125–600 minutes, Mann–Whitney U-test, \(p=0.84\); SC: median 8.5 sessions, IQR 3–10 sessions, CR: median 9 sessions, IQR 4–13 sessions, Mann–Whitney U-test, \(p=0.20\)).

**Did cognitive remediation improve cognition?**
Cognitive remediation did not predict differences in global cognition scores [intercept (baseline) –1.7, 95% CI –7.7 to 4.4, \(p=0.59\); gradient (group × time) –0.73, 95% CI –1.84 to 0.38, \(p=0.20\)]. However, after the intervention the CR group completed significantly more WCST categories: after CR, 74% completed five categories (range 4–5 categories); after SC, 63% completed five categories (range 2–5 categories) [adjusted odds ratio (OR) 2.9, 95% CI 1.3 to 6.9; \(p=0.012\)]. By final follow-up these gains were lost (adjusted OR 0.7, 95% CI 0.2 to 2.5; \(p=0.61\)). The median score for complex...
FIGURE 2 Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing participant flow through the trial.
figure copying was 35 (IQR 33–36) after CR and 33 (IQR 29–35) after SC (p = 0.11, Mann–Whitney U-test). After removing an outlier with persistent, specific, severe visuospatial impairment (baseline copying score 12; range of other participants’ scores 24–36, mean 32.89, SD 3.89; Dixon’s Q59 0.50, p < 0.01), CR had a trend towards better scores at 12 weeks (adjusted OR 3.83, 95% CI 0.99 to 14.77; p = 0.052) but not at the final assessment (adjusted OR 1.6, 95% CI 0.3 to 7.7; p = 0.56).

**Did cognitive remediation improve the efficacy of cognitive–behavioural therapy for psychosis?**

**Symptoms**

Cognitive remediation was not associated with significantly lower PSYRATS scores over the period of study (Figure 3) (intercept –2.8, 95% CI –10.7 to 5.2, p = 0.50; gradient 0.3, 95% CI –0.4 to 1.1, p = 0.39). The effect of CR on the PANSS score was non-significant (intercept 3.8, 95% CI –2.7 to 10.3, p = 0.25; gradient –0.4, 95% CI –1.5 to 0.6, p = 0.44). Eight participants in each allocation group had full remission of symptoms on the PSYRATS (OR 0.96, 95% CI 0.26 to 3.51; p = 1.00, Fisher’s exact test), giving a number needed to harm with CR of 116 (95% CI ranging from a number needed to treat of 3 to a number needed to harm of 12).

However, insight changed significantly more positively after CR than after SC (intercept –1.9, 95% CI –27.7 to 23.8, p = 0.88; gradient 0.55, 95% CI 0.08 to 1.01, p = 0.02). At 42 weeks the median insight score was 12 after both CR and SC, but the IQRs after CBTp (CR 9.5–13; SC 6–13) showed that fewer participants in the CR group had substantially impaired insight. There was no significant effect of CR on SOFAS score, depression or self-esteem.

### TABLE 3 Group demographic and clinical characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>CR</th>
<th>SC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21 (68)</td>
<td>16 (53)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>23 (74)</td>
<td>25 (83)</td>
</tr>
<tr>
<td>African and African Caribbean</td>
<td>1 (3)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>South Asian</td>
<td>5 (16)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>East Asian</td>
<td>2 (7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>26 (84)</td>
<td>26 (87)</td>
</tr>
<tr>
<td>Schizoaffective disorder</td>
<td>5 (16)</td>
<td>4 (13)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>24.7 (5.2)</td>
<td>23.4 (4.4)</td>
</tr>
<tr>
<td>Full-time education (years), median (IQR)</td>
<td>13 (11–14)</td>
<td>13 (11–14)</td>
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<td>13 (8–22)</td>
<td>16.5 (11–35)</td>
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<td>71.3 (13.9)</td>
<td>69.5 (11.7)</td>
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<td>IQ, mean (SD)</td>
<td>105.4 (8.0)</td>
<td>103.4 (10.0)</td>
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<td>Global cognition, mean (SD)</td>
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<td>100.5 (16.4)</td>
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<td>5 (4–5)</td>
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<tr>
<td>Complex figure copying, median (IQR)</td>
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<td>34 (31–35)</td>
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<tr>
<td>Defined daily dose, median (IQR)</td>
<td>0.75 (0–1.06)</td>
<td>0.72 (0.31–1.00)</td>
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</tbody>
</table>

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NIHR Journals Library www.journalslibrary.nihr.ac.uk
Repeating multiple regressions for clinical and neuropsychological variables, weighting cases according to the probability of dropout, did not alter the significance of the results.

**Relapse and readmission**

Cognitive remediation had no significant effect on time to relapse (adjusted HR 1.4, 95% CI 0.5 to 3.5; \( p = 0.50 \)) or readmission (adjusted HR 1.2, 95% CI 0.2 to 5.5; \( p = 0.84 \)).

**Did cognitive remediation improve the efficiency of cognitive–behavioural therapy for psychosis?**

After CR, far fewer sessions of CBTp were required (Figure 4): a median of seven (IQR 2–12) sessions compared with a median of 13 (IQR 6–18) sessions for the SC group (\( p = 0.039 \), Mann–Whitney \( U \)-test). CR still predicted fewer sessions of CBTp after adjustment for potential confounders (coefficient \(-1.0, 95\%\) CI \(-0.3\) to \(-1.7\); \( p = 0.011 \)). Unmasking was not responsible: their allocation of 53 participants remained masked from therapists and the median number of sessions was six (IQR 1–12) after CR and 15 (IQR 7–19) after SC (\( p = 0.012 \), Mann–Whitney \( U \)-test). Allocation was unmasked for eight participants, for whom the median number of sessions was 14 (IQR 10–18.5) after CR and nine (IQR 3–18.5) after SC (\( p = 0.37 \), Mann–Whitney \( U \)-test).

There was no evidence that level of formulation differed between the CR group and the SC group across all participants (adjusted OR 1.1, 95% CI 0.2 to 6.1; \( p = 0.88 \)) or in masked patients alone (adjusted OR 0.7, 95% CI 0.2 to 2.3; \( p = 0.50 \)).
Discussion

Although the hypothesis that CR would enhance the effect of CBTp on symptoms was rejected, the hypothesis that it would improve the efficiency of CBTp was supported. After CR, participants made the same amount of progress in half the number of CBTp sessions. If CBTp ended when a therapist judged that the client had progressed cognitively as far as possible, then better engagement because of improved insight and cognition after CR might have helped client and therapist reach this point more quickly. If symptom reduction determined when therapists ended CBTp, less efficient CBTp after SC could have led therapists to lengthen the duration of CBTp to compensate. Either would explain why efficiency rather than efficacy improved.

The CR group had fewer low scores on the IS at 42 weeks. The difference from the SC group became substantially greater after CBTp than before and so it appears most likely that CR enhanced CBTp and this led to relatively better insight. CR improved WCST performance, although this was not sustained. The WCST is one of the most common, robust and sensitive measures of CR outcome\cite{16} and frequently predicts progress in social skills and CR interventions\cite{43}, particularly categories complete (schema generation)\cite{54}. Silverstein and colleagues\cite{15} previously proposed that transient cognitive benefits could promote sustained changes in behaviour and performance during succeeding interventions, consistent with transient neuropsychological gains facilitating CBTp.

Global cognition did not improve but other neuropsychological measures might have been less accurate than the WCST. Short, less-demanding cognitive tasks were chosen for these process measures, mindful of the risk of alienating potential and actual participants and rendering the sample unrepresentative. Although these tasks had demonstrated validity in other trials (see Table 1\cite{1}), they lacked the rigor of lengthier cognitive batteries [e.g. the MATRICS Consensus Cognitive Battery (MCCB)]\cite{60}, making them vulnerable to practice effects that could have concealed the benefits of CR. Nevertheless, other CR trials with more extensive batteries found that executive function effect sizes exceeded other types of cognition\cite{55,61}, suggesting that the difference was real.

![Figure 4: Number of sessions of CBTp by allocation group.](https://www.journalslibrary.nihr.ac.uk)
One limitation of our study was that inexperienced therapists delivered CR. In addition, CBTp was delivered by NHS clinicians who, although qualified and supervised, were not research trained and supervised (although CBTp quality scores were reasonably good). Even so, we felt it important to accept these limitations to simulate routine clinical practice and make generalisation credible. One consequence of our naturalistic design was that the median number of CBT sessions was lower than that recommended by NICE guidelines; however, they still appeared sufficient to have an effect. A strength of the naturalistic trial design was that NHS early-intervention services take nearly all incident cases of schizophrenia in their catchment areas and so attendees at these services are reasonably representative of all those who might benefit from CBTp.

Another strength of our trial was that contact time was well matched between the CR group and the SC group, ensuring plausible matching of non-specific benefits of remediation. Even the most carefully designed randomised trials of combination therapy, for instance CR with social skills training or with vocational interventions, struggled to match exposure to the intervention and comparison conditions. However, SC offered more opportunity for non-directive listening than task-oriented CR. This compensatory therapeutic effect could have led us to underestimate the specific benefits of CR.

Allocation was almost completely masked from assessors, whereas previous trials combining psychosocial interventions have often been open. Although it is unclear how far measurement of neuropsychological performance or employment rates is affected by the open rating, previous meta-analysis of CBTp suggests that symptoms are sensitive, as limiting inclusion to studies with masking and other rigorous design features diminished the effect size of CBTp from 0.40 to 0.22. Although it was difficult to mask allocation from CBTp therapists, they identified allocation in only 13% of participants. In fact, unmasking only attenuated the difference in CBTp length between the CR group and the SC group: the reduction in CBTp length after CR was greater in those participants with allocation still masked.

Overall, our findings suggest that CR delivered by relatively unskilled workers improved the efficiency of subsequent CBTp, enabling participants and therapists to achieve the same amount of progress in therapy in approximately half the number of sessions. The computer-aided CR approach that we selected was delivered by relatively inexpensive support workers within a typical clinical service. Labour costs for a course of CR were only £85. A substantial increase in the efficiency of CBTp implies that the same number of CBTp therapists could treat many more patients, whereas estimates from previous studies imply that the shortened duration of CBTp was equivalent to a saving of £335 per patient.

**Key findings**

- Cognitive remediation after first episodes of non-affective psychosis improved executive function but no other neuropsychological test scores.
- After CR, the duration of CBT was much shorter but there was no difference in efficacy.
- At the end of CBT, those who had received CR had significantly better insight.
Chapter 2 Healthy living workstream: development of an intervention to encourage activity, improve diet and control weight gain (InterACT) and a randomised controlled trial


**Abstract**

**Background:** People with psychosis are at an increased risk of weight gain, contributing to poor physical health and early death.

**Objectives:** (1) Develop an effective and acceptable healthy-living intervention to prevent weight gain for people with psychosis, (2) evaluate the clinical effectiveness of the intervention and (3) evaluate the acceptability of the intervention.

**Methods:** The intervention was developed by synthesising the results of a number of inter-related studies including (1) a review of healthy-living intervention studies, (2) qualitative interviews with service users and health professionals, (3) identification of a theoretical model and (4) cultural adaptation of the intervention. It was tested with service users of two early-intervention services with a body mass index (BMI) ≥ 25 kg/m², who were randomly allocated to the intervention group or usual care. The primary outcome was change in BMI from baseline to 12 months’ follow-up. Qualitative interviews were conducted with participants about their experience of the intervention.

**Results:** The intervention consisted of eight individual sessions with a trained support, time and recovery (STR) worker, supplemented by optional group activities. In total, 105 participants were recruited (54 intervention group, 51 usual-care group), with 89% retention at 12 months. There was a small but non-significant decrease in mean BMI at 12 months in the intervention group compared with no change in the usual-care group. The intervention was highly acceptable to participants.

**Conclusion:** The healthy-living intervention was associated with a small but non-significant reduction in BMI in the intervention group but not in the usual-care group.

**Introduction**

Individuals with psychosis have poorer physical health and die younger than other members of the general population. Recent government policy has set targets for service providers to reduce this inequality. One major contributory factor of poor physical health may be the rapid weight gain associated with the prescription of second-generation antipsychotic drugs. A review by Foley and Morley showed average weight gain to be 5–6 kg after only 6–8 weeks of treatment with antipsychotic drugs, with unhealthy cardiometabolic changes already beginning to emerge. Commenting on the review, an editorial in the *Lancet* stated that in any other scenario the responsible physician would seek an alternative treatment.
However, for mental health professionals and their patients there are no realistic alternatives currently available. If, as the editor suggests, patients must continue to take antipsychotic medication, then there is an urgent need to develop interventions to help patients control their weight gain and protect themselves against the cardiometabolic effects and complications associated with weight gain.

Although conclusions from a Cochrane review showed that there is insufficient evidence to support the general use of pharmacological interventions for weight management in people with schizophrenia,69 there is sufficient evidence in support of non-pharmacological interventions. A meta-analysis of non-pharmacological weight management studies in people with psychosis70 showed that CBT and nutritional counselling were effective at reducing or slowing antipsychotic medication-induced weight gain. However, benefits rapidly attenuated once the intervention was discontinued.71 An explanation for these modest effects and poor durability may lie in the development of the interventions. For the most part the interventions in the review were not obviously underpinned by theoretical models of behaviour change. For example, there was limited reporting of service users’ motivations for weight control, their beliefs about their ability to control their weight or the strategies that they would use to regulate their behaviour. Furthermore, it was not clear which (if any) of these factors were addressed in the interventions (and how). Additionally, the acceptability of interventions to service users and those delivering them was not assessed. Finally, only one study in the review had recruited patients in the early stages of treatment for psychosis.

In the last decade there has been growing interest in the development and evaluation of interventions, largely driven by the influential UK Medical Research Council (MRC) framework.72 The MRC defines a ‘complex intervention’ as one in which there is ambiguity over the ‘active ingredients’ of the intervention and their optimal mix, and the phased development of such interventions has been advocated.72 This involves the use of theoretical and empirical work to identify the active ingredients of the intervention (modelling), followed by an exploratory randomised controlled trial (RCT) to test the intervention, examine its delivery in routine settings and provide estimates of key trial parameters such as recruitment rates and effectiveness. In this chapter we will describe how, guided by the MRC framework,72 we have developed and tested the feasibility, acceptability and effectiveness of a novel lifestyle intervention that aims to help people with first-episode psychosis control their weight.

The overall aim of the workstream was to develop an evidence-based, acceptable, feasible and effective intervention to encourage activity, improve diet and control weight gain in people recovering from a first episode of psychosis and to evaluate its clinical effectiveness and cost-effectiveness in an exploratory randomised controlled study. We conducted two key phases.

**Phase 1: development**

Phase 1 had two key aims:

1. to identify the active ingredients of a healthy-living intervention to control weight in people after a first episode of psychosis
2. to develop an evidence-based, acceptable and feasible protocol and training programme for the delivery of a healthy-living intervention.

To develop the intervention we conducted a series of separate but inter-related studies, the findings of which were synthesised to produce a prototype healthy-living intervention (**Figure 5**). We (1) identified the evidence base by updating a systematic review, (2) identified the most appropriate theoretical model to underpin the intervention, (3) conducted qualitative interviews with service users to examine their beliefs about weight gain in psychosis, (4) conducted both focus groups and individual interviews with mental health professionals to examine their perspectives and (5) culturally adapted our intervention to be appropriate to the needs of the ethnically diverse population that we were working with. These data were synthesised by the trial team and the draft prototype healthy-living intervention was then subject to (6) a stakeholder consensus group to finalise the intervention.
The study aimed to update a systematic review of the RCT literature and then conduct a meta-regression to identify:

- the types and relationships between components of non-pharmacological interventions used to improve healthy-lifestyle behaviours (all interventions used to improve healthy-lifestyle behaviours including exercise, diet and weight maintenance) in people with psychosis
- the overall clinical effectiveness of non-pharmacological interventions for people with psychosis
- the factors associated with effective interventions such as setting (inpatient/community), delivery mode (group/individual) and personnel delivering the interventions.

Methods
We drew on a recently published high-quality systematic review of non-pharmacological management studies of antipsychotic medication-related weight gain. We supplemented this by searching for any additional RCTs using the Cochrane Central Register of Controlled Trials (CENTRAL). The search of CENTRAL was then amplified by searches of MEDLINE, EMBASE, PsycINFO, the Health Technology Assessment database, the Allied and Complementary Medicine Database, Science Citation Index and Social Sciences Citation Index, the National Research Register and the System for Information on Grey Literature in Europe. The reference lists of all identified studies and review papers were searched for other relevant publications up to 2007 to identify recent additional literature. Searches (available from the authors) utilised a mixture of subject headings and free-text terms.

Inclusion criteria

- **Study design.** RCTs in which the majority (> 50%) of the participants were diagnosed with a psychotic disorder.
- **Study context and population.** Populations eligible for inclusion included any adult group with a psychotic mental health problem using any criteria (e.g. ICD-10 criteria, DSM-IV criteria or case note diagnosis) seeking treatment with a non-pharmacological intervention to improve healthy living or prevent weight gain. All settings including community, primary care, specialist outpatient and inpatient and non-clinical settings were eligible.
• **Interventions.** Lifestyle/healthy-living/health-education interventions focusing on healthy eating and/or physical activity or a combination of both delivered on either a group or an individual basis.

• **Outcomes.** Primary outcome measures included self-reported and externally assessed aerobic fitness, blood pressure, weight, BMI, flavouval antioxidants, abdominal girth measurement, waist-to-hip ratio and/or other outcomes of measured compliance with recognised healthy-living guidelines. Secondary outcomes included psychiatric symptoms, quality of life, self-esteem, self-efficacy, medication compliance, medication dosage, attitude or belief change, numbers lost to follow-up and number of participants approached who declined to participate in the study.

**Exclusion criteria**
Studies that focused exclusively on smoking cessation or reducing the use of illicit substances, non-randomised studies and those not written in the English language were excluded.

**Data extraction and quality assessment**
Eligibility judgements and data extraction were carried out independently by two reviewers. No formal measure of the reliability of data extraction was calculated but disagreements were resolved by discussion with members of the trial team.

**Analysis**
We completed a meta-analysis of these studies using random-effects modelling to provide an overall pooled measure of effect on BMI rather than weight as in the review by Álvarez-Jiménez and colleagues. In addition, we conducted a meta-regression on intervention moderators to examine the relationship between components of the intervention and outcomes, to determine potentially critical ingredients.

**Results**
Three additional studies were identified. We identified 12 studies in total\(^73\)\textsuperscript{–}\textsuperscript{85} Eleven compared the intervention with routine care and one\(^80\) used brief nutritional education as a control. The review by Álvarez-Jiménez and colleagues\(^70\) found that weight-management interventions resulted in a mean weight difference of 2.56 kg compared with treatment as usual (TAU). No difference in efficacy was shown between interventions delivered to groups and interventions delivered to individuals or between CBT interventions and nutritional counselling. Similar to the review of Álvarez-Jiménez and colleagues,\(^70\) our analysis showed that weight-management interventions are moderately effective, resulting in an average change in BMI of approximately 1 point (–0.708, 95% CI –1.07 to –0.349; Figure 6). We found no difference between studies that were CBT based and studies based on other therapeutic approaches. Unlike the study by Álvarez-Jiménez and colleagues,\(^70\) our analysis showed a trend towards greater effectiveness for individual interventions compared with group interventions [standardised mean difference (SMD) –1.153 (95% CI –2.57 to 0.27) vs. SMD –0.533 (95% CI –0.73 to –0.32) respectively]. In general, the effect of these interventions attenuated rapidly once the intervention had ceased. None of the reports indicated that the components of the intervention were underpinned by a specific psychological model of behaviour change and only one study had focused specifically on people with early psychosis.\(^76\)

**Key findings**
- Weight management interventions are moderately effective, with an average change in BMI of approximately 1 point or an average weight loss of 4% body weight. Effects seem to attenuate once the intervention stops, although most studies did not conduct follow-up assessments beyond 3 months.
- Interventions that aimed to prevent weight gain were more effective than those that targeted weight loss.
- Interventions that were delivered to individuals were more effective than those delivered solely to groups.
- Interventions that have a supervised exercise component may be more effective than those that do not.
- None of the interventions was underpinned by a specific psychological model of behaviour change.
<table>
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<tr>
<th>Study name</th>
<th>Outcome</th>
<th>Time point</th>
<th>Std diff. in means</th>
<th>Standard error</th>
<th>Variance</th>
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<th>Upper limit</th>
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Effect size measured by standardised BMI difference

FIGURE 6 Forest plot showing the effectiveness of healthy-living interventions. Std diff., standard difference; Tx, treatment.
**Qualitative interviews with service users**

**Aim**
To explore users’ views of illness and treatment beliefs, healthy living, preferences with regard to healthy-living interventions and barriers to and facilitators of healthy-living interventions.

**Methods**
All patients from an early-intervention service in the north-west of England (n = 260) were contacted to participate in interviews to ensure inclusion of a range of patient baseline characteristics (i.e. age, gender and ethnicity) to ensure a diversity of views. Semistructured interviews with consenting participants were conducted in patients’ homes by the researcher. An interview guide (see Appendix 1) was designed by the trial team to ensure exploration of key areas, including illness and treatment beliefs, beliefs about psychosis, obesity and weight control, antipsychotic medication and its side effects, current dietary, exercise and smoking habits and barriers to and facilitators of healthy-living interventions, and to establish preferences about key aspects of a potential healthy-living intervention including content, setting, format and delivery of the intervention. Interviews were digitally recorded and lasted between 30 and 45 minutes.

**Analysis**
Interviews were transcribed verbatim and data were analysed using framework analysis. An initial coding framework was developed and transcripts were checked against the framework to ensure that there were no significant omissions. Codes in each interview were examined across individual transcripts as well as across the entire data set and allocated to the framework. Using the constant comparative method of analysis, broader categories used linked codes across interviews. Data were interpreted and analysed within the framework to distil, interpret and structure component statements about illness beliefs, healthy living and the intervention. Direct quotes are given an ID number and other characteristics have been removed to ensure anonymity.

**Results**
In total, 13 service users were interviewed. 10 were male and the mean age was 25.5 years (range 19–32 years). With regard to ethnicity, two were black African, eight were white British and three were South Asian. Ten participants were taking antipsychotic medication, one was taking a mood stabiliser and two were not taking any medication. Eight were unemployed, three were employed part-time, one was employed full-time and one was a student.

Three key themes in the data related to:

1. illness and treatment beliefs about weight gain and the role of medication
2. current lifestyles and perceptions of health risks
3. preferences regarding the type of healthy-living intervention.

These are briefly summarised in the following sections.

**Illness and treatment beliefs**
Service users’ descriptions about the onset of their psychosis and their initial reaction to symptoms reflected the individualistic and varied nature of their experiences. Two themes emerged from these explanations: (1) a response to stress resulting from life events and (2) the use of illicit substances including cannabis and ecstasy. Participants reported that lack of sleep, stress and stigma made their symptoms worse whereas a good sleep pattern and social support improved symptoms.

Participants taking antipsychotic medication expressed positive views regarding its helpfulness. The key negative views about medication were that it resulted in increased appetite, weight gain, tiredness and lethargy. All participants said that they had gained weight since starting antipsychotic treatment.
The average self-reported weight gain was 10.5 kg. Participants had been given information about possible weight gain but had not understood why this was likely to happen or what they should do to prevent it.

The doctor mentioned it. He said that when you’re taking this medication you could put on a bit of weight . . . because the water content in your body increases and so when you feel hungry you sort of want to eat more, there’s an increase of water in your body and you put on weight but it’s easily counteracted if you remain fit and active and if you take regular exercise it’ll automatically go.

Some participants believed that they had not received sufficient information to manage the side effects, including increased appetite, which led to binge eating, and drowsiness, leading to reduced levels of physical activity, both of which were believed to have contributed to weight gain.

**Current lifestyles and perceptions of health risks**

Most participants felt that they had a fairly healthy lifestyle in relation to dietary intake and level of physical activity and thought that this was important to prevent further weight gain, although more than half smoked. Participants believed that early in their recovery from the episode of psychosis the amount of physical activity they had undertaken had reduced but that this had improved as recovery progressed. Weight gain was not seen as posing a current health risk but could in the future. Participants’ awareness of the degree and risk of weight gain was limited. Two participants viewed their weight gain as positive, as they had previously been underweight. Most were confident that they could manage weight gain through diet and exercise. Motivation to lose weight included the desire to stay fit and healthy and to regain their pre-illness body image.

I think I’m not too overweight but not where I want to be, really . . . about 12.5 stone, something like that. I’m not particularly bothered about the weight, it’s more like the beer belly kind of look, you know? I’d rather be . . . you know, I don’t want to be some big muscly . . . it’s the appearance. It’s the not the weight aspect, it’s the appearance, really.

**Preferences regarding the type of healthy-living intervention**

There was a mixed response to the question of whether a healthy-living intervention should be delivered on a group or an individual basis. Participants who placed greater importance on social interaction favoured a group intervention. No specific preference was expressed about who should facilitate the intervention and suggestions included a community mental health nurse, a support, time and recovery (STR) worker or an expert such as a physical fitness trainer or dietitian. Participants wanted the intervention to be cost neutral to them and, therefore, based locally. A strong preference was expressed for an intervention that could provide the opportunity to undertake physical activity, rather than being focused on education. Potential barriers to success expected by service users included financial barriers to participation, work hours, problems with memory and concentration and fluctuating motivation.

I think something cardiovascular. If people have got weight gain then the best way to maintain a healthy heart and to burn these calories off . . . because I think the medication makes people retain the weight much more worse than what they would do normally so you need to do things like running and rowing machines, things like that, access to the gym . . . Or maybe even learning how to do a few exercises at home for people who have got, I don’t know, agoraphobia and stuff like that where they’ve got a fear of going to places and meeting new people, maybe exercises at home that they can do.
Key findings

- Most participants had gained weight and they attributed weight gain to an increased appetite and drowsiness from taking antipsychotic medication.
- Most participants felt that managing the increase in their appetite and staying physically active to prevent further weight gain were important issues to them.
- Participants perceived a low level of risk to their current health because of the weight that they had gained but many were sufficiently concerned about it to be taking some active steps to manage it and would be motivated to accept additional help were it to be made available.
- Participants expressed specific preferences regarding the type of healthy-living intervention that would be acceptable, which needed to be active, promote physical activity, be geographically accessible, be cost neutral and be delivered flexibly on an individual or a group basis according to personal preference.

Qualitative interviews and focus groups with health professionals

Aim

To explore health professionals’ views of their respective roles and responsibilities in the area of physical health care and the feasibility and acceptability of a healthy-living intervention for people experiencing a first episode of psychosis.

Methods

All qualified health professionals from three early-intervention service teams in a north-west of England early-intervention service were asked to participate in the study. Consenting participants were given the option of a telephone interview or a focus group. An interview guide (see Appendix 2) was developed by the trial team to ensure exploration of key areas with regard to the healthy-living intervention, including participants’ views of their respective roles and responsibilities in the area of physical health care, the need for and capacity to deliver the suggested intervention and barriers to and facilitators of its uptake in various settings (e.g. community, secondary, primary). Interviews and focus group were digitally recorded.

Analysis

Interviews were transcribed verbatim. The interview data were analysed using the principles of framework analysis.87

Results

In total, 14 health professionals consented (eight were interviewed individually and six attended a focus group). All health professionals recognised the importance of monitoring their clients’ physical health, which included their weight, and were in agreement that their clients’ lifestyle should be monitored. They felt that any healthy-living intervention should focus on food intake, exercise, alcohol use, smoking and substance misuse. Participants felt that they had received insufficient training on physical health and health promotion. The majority were aware of weight gain in service users as an important and distressing side effect.

“I’ve got quite a few young women who’ve been quite resistant to some medications because of the likely increase in weight and things like that.”

HP4

Case managers welcomed the idea of a specific healthy-living intervention and clearly highlighted the benefits to patients. Health professionals felt that the healthy-living intervention should identify service users’ current health behaviours and provide information about improving health and assistance with behaviour change. Health professionals felt that the key components of a healthy-living intervention should address (1) healthy eating, including buying healthy foods on a budget, cooking skills and recipes, (2) the risks of weight gain and how to monitor weight, (3) exercise: what is available, physically possible, affordable and accessible, (4) dental hygiene, (5) substance misuse and (6) physical health monitoring such as blood checks.
The ideal format of an intervention was seen as a mix of group and individual sessions, which should be informal, relaxed, local and delivered within a sufficient timescale to allow for behaviour change and the maintenance of new behaviours. Although health professionals recognised the benefits of a healthy-living intervention, they felt that they did not have the necessary time or expertise to deliver the intervention and felt that STR workers were most appropriately placed to do so.

Well my own personal, if it was up to, you know like you say in my power I’d be looking at kind of it being you know like a couple of the STR workers who are particularly interested in that and leave it up to and empowering them, letting them you know have, putting out the guidelines where they want to go, because again they tend to have, you know, a better relationship.

**Key findings**

- Health professionals felt that the monitoring of clients’ physical health and lifestyle was part of their day-to-day work but they were less optimistic about their own role in providing a healthy-living intervention.
- The ideal format of an intervention was seen as a mix of group and individual sessions, which should be informal, relaxed, local and on a sufficient time scale to allow for behaviour change and the maintenance of new behaviours.

**Theoretical framework**

The common-sense model (CSM) of self-regulation[^89] was chosen as the theoretical framework for the healthy-living intervention because it provides guidance on both motivation and the implementation of behaviour change. In the context of rapid weight gain in early psychosis, the CSM would suggest that people’s motivation to lose weight, and the behaviours selected to pursue that goal, depend on their personal beliefs about, or models of, the weight gain – what is causing it, what its consequences will be and how controllable it is. These personal models are influenced by information gained from abstract (knowledge-based) and concrete (experiential) sources. Furthermore, the CSM suggests that people are more likely to change (e.g. to eat more healthily and to exercise more) if they develop belief-congruent[^90] ‘if–then’ action plans that they can use to regulate their behaviour. Feedback plays an important role in the CSM, as it suggests that behavioural attempts to regulate weight gain will be appraised and will feed back into both beliefs and subsequent behaviours. Thus, the model suggests combining motivational approaches (including education to bring about belief change) with action-planning interventions and the opportunity to review the effectiveness of changed behaviour.[^90] Therefore, the CSM suggested that when planning our intervention we should begin by assessing participants’ own perceptions of their health and weight gain. By doing so we could then ensure that information about healthy living that was provided would be tailored to the needs of each individual. There would also need to be monitoring of the impact of behavioural feedback (e.g. increasing activity levels) on beliefs and of belief change on behaviour. A variety of techniques to modify perceptions would be incorporated to help service users benefit from abstract (knowledge-based) information derived from their own experiences of weight gain. Action planning would be incorporated, with goals set in accordance with motivational beliefs, plans would be developed to regulate behaviour (including using helpful cues and overcoming potential barriers) and explicit monitoring of the effectiveness of behaviour would be carried out.

**Cultural adaptations**

The area where the study was conducted had a large South Asian population, particularly among the younger members of the community who were likely to access the early-intervention service. In recognition of the importance of culture in influencing lifestyle factors such as diet and exercise, we used the relevant literature[^91] and consulted with one of the authors (NH) who has expertise in developing and delivering culturally sensitive interventions. Using both sources we identified the key issues that would need to be addressed to: NHRI Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

[^89]: Common-sense model
[^90]: CSM
[^91]: Literature
Urdu, which was still spoken by older family members. Some of the healthy living materials that were developed needed to have culturally specific advice such as information on healthy eating in specific communities. Personnel involved in the delivery of the intervention needed to have a cultural understanding and awareness of the ethnic groups with whom they were working.

**Synthesis**

The research team held a 2-day workshop meeting in August 2008 to synthesise the data collected and model the draft intervention. The synthesis meeting was conducted in two stages. In the first stage members of the study team presented the findings of each of the preliminary studies, which were then summarised (Table 4). The second stage involved interactive exercises and discussions, focusing on the possible content, duration and delivery of the intervention, drawing on the evidence presented in Table 4. The aim of this stage was to determine the optimum content, delivery and duration of the intervention as well as who should deliver it, what training they would require and any additional materials that might be needed (Table 5).

**TABLE 4 Key findings**

<table>
<thead>
<tr>
<th>Systematic review and meta-regression</th>
<th>Qualitative interviews with users experiencing first-episode psychosis</th>
<th>Qualitative interviews with health professionals working in early-intervention services</th>
<th>Core dimensions of the self-regulation model</th>
<th>Incorporation of cultural issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>An individual intervention is likely to be more effective than a group intervention</td>
<td>Interventions need to be free and geographically accessible</td>
<td>Case managers think that they do not have the time to deliver a healthy-living intervention</td>
<td>Partly individualised</td>
<td>Need to recognise the role of families in decision-making</td>
</tr>
<tr>
<td>Lifestyle interventions are effective in promoting weight loss but this only borders on clinical significance and falls below this at 6 months’ follow-up</td>
<td>Preference for an active intervention rather than a purely educational intervention</td>
<td>STR workers or assistant case managers are more likely to be delivering the more time-consuming and active interventions</td>
<td>Needs measures of representations</td>
<td>Workers delivering the intervention would need some training in cultural awareness</td>
</tr>
<tr>
<td>Length of follow-up is insufficient to see longer-term gains and there was rapid attenuation of effects over time</td>
<td>Mixed views on group vs. individual interventions</td>
<td>Case managers thought that promoting healthy living in service users was important</td>
<td>Development and monitoring of action plans</td>
<td>Need to explore families’ as well as individuals’ explanatory models of poor health</td>
</tr>
<tr>
<td>In terms of key components, actual exercise seems to enhance outcome</td>
<td>Information provided about healthy living was from variable sources and of variable content</td>
<td>Case managers had clear ideas about what the content of a healthy-living intervention should be</td>
<td>Variety of methods for presenting information</td>
<td>As an engagement strategy for the intervention, emphasise the cultural sensitivity of the intervention</td>
</tr>
<tr>
<td>The difference in effect size between preventative trials and weight loss trials is minimal</td>
<td>Service users perceived a low level of risk from the weight gained</td>
<td>Early intervention around healthy eating is important</td>
<td>Focus on behaviour and emotion</td>
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<td></td>
<td></td>
<td>Cost and accessibility</td>
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<tr>
<td></td>
<td></td>
<td>Healthy-living interventions can be individualised in a group setting</td>
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</tbody>
</table>
### TABLE 5 Active ingredients of the healthy-living intervention

<table>
<thead>
<tr>
<th>Component</th>
<th>Systematic review</th>
<th>User interviews</th>
<th>Professionals interviews/focus groups</th>
<th>Self-regulation model</th>
<th>Cultural adaptations</th>
<th>Incorporated into the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td>Supervised/actual exercise</td>
<td>Preference for an intervention that includes exercise and healthy eating</td>
<td>Information about diet</td>
<td>Cognitive component to elicit personal/cultural beliefs about weight gain and being overweight</td>
<td>Provide information in key languages</td>
<td>Emphasis of the intervention should include healthy-living advice, active and participatory exercises involving actual physical activity, and diet-related activities. Specific collaborative action plans will be developed and monitored throughout the intervention.</td>
</tr>
<tr>
<td></td>
<td>Systematic review showed rapid attenuation of effects over time, indicating that maintaining exercise is important if gains are to be maintained</td>
<td>Interventions need to include active user participation, e.g. using the gym, cooking</td>
<td>Intervention to include physical activity</td>
<td>Need to include South Asian families in the intervention</td>
<td>Need to provide information about risks to health beliefs which are part of the intervention as well as outcomes</td>
<td>There needs to be a strong emphasis on maintenance of the healthy-living intervention, which aims to incorporate health changes into the individual's lifestyle and reduce rapid attenuation of effect.</td>
</tr>
<tr>
<td></td>
<td>Preference for an intervention that includes exercise and healthy eating</td>
<td>Express a need for help in maintaining healthy-living changes</td>
<td>Dietary advice should be active (e.g. luncheon group)</td>
<td>Intervention needs to include factual information about healthy living</td>
<td></td>
<td>Maximising strategies to engage families and carers in facilitating and implementing the exercise and dietary advice is important.</td>
</tr>
<tr>
<td></td>
<td>Interventions need to include active user participation, e.g. using the gym, cooking</td>
<td>Strategies to combat tiredness and sedation</td>
<td>Needs to be enjoyable</td>
<td>Needs to be self-regulation model measures of health beliefs which are part of the intervention as well as outcomes</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Preference for an intervention that includes exercise and healthy eating</td>
<td>Need to provide information about risks to health for people with unhealthy lifestyles</td>
<td>Targeting poor motivation/lack of energy</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Preference for an intervention that includes exercise and healthy eating</td>
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<td></td>
</tr>
</tbody>
</table>

continued
<table>
<thead>
<tr>
<th>Component</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Service users saw healthy-eating groups as an opportunity to socialise/share experiences</td>
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<td></td>
<td></td>
<td>Must be client centred Groups have a social component</td>
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<td></td>
<td></td>
<td>Include various methods of presenting information</td>
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<td></td>
<td></td>
<td>Essential to elicit people’s health/cultural beliefs to maximise engagement and individualise the intervention</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Important to provide some exercise and dietary group activities to promote social cohesion and sharing of experiences between users</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Intervention needs to be population specific to ensure that it addresses specific barriers (i.e. motivation and fatigue)</td>
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<td></td>
<td></td>
<td></td>
<td>Needs to be cost neutral and geographically accessible</td>
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<td></td>
<td></td>
<td>None noted</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Mixed model – providing both individual (i.e. one-to-one) plus group sessions dependent on patient preference</td>
</tr>
</tbody>
</table>

**Format:** Individual/group/mixed model

- Slight benefit for individual over group intervention
- Mixed views on preference for group vs. individual interventions
- Individualised component necessary
- Needs individual component regarding individual health beliefs
- None noted
<table>
<thead>
<tr>
<th>Component</th>
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<th>Self-regulation model</th>
<th>Cultural adaptations</th>
<th>Incorporated into the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who should deliver the intervention</td>
<td>Varied</td>
<td>No preference expressed</td>
<td>Case managers with an interest in physical health (protected time), experts in physical health, STR workers/assistant case managers</td>
<td>Worker needs to have knowledge of the self-regulation model</td>
<td>Worker needs to have knowledge of cultural issues, particularly South Asian</td>
<td>Funding parameters mean that a STR worker will be employed to deliver the intervention and training in the self-regulation model and knowledge of cultural issues (particularly South Asian). A user will be engaged to deliver some of the group activities</td>
</tr>
<tr>
<td>Setting of the intervention</td>
<td>Not relevant</td>
<td>Should be local and accessible (travel and cost)</td>
<td>Type of venue not important</td>
<td>None noted</td>
<td>Geographically accessible</td>
<td>Cost and accessibility are key issues and will be addressed by the STR worker to ensure affordability and a suitable location</td>
</tr>
<tr>
<td>Number/duration of sessions</td>
<td>Not relevant</td>
<td>None relevant</td>
<td>None noted</td>
<td>Decide on the optimum number of sessions of physical activity</td>
<td>None noted</td>
<td>Booster sessions/intervention delivered over an extended period to ensure incorporation of healthy living into the individual’s lifestyle</td>
</tr>
</tbody>
</table>

Who should deliver the intervention:
- Varied
- No preference expressed
- Case managers with an interest in physical health (protected time), experts in physical health, STR workers/assistant case managers
- Worker needs to have knowledge of the self-regulation model
- Worker needs to have knowledge of cultural issues, particularly South Asian

Setting of the intervention:
- Not relevant
- Should be local and accessible (travel and cost)
- No preference regarding setting
- Type of venue not important
- None noted
- Geographically accessible

Number/duration of sessions:
- Not relevant
- None relevant
- None noted
- Decide on the optimum number of sessions of physical activity
- None noted
- Booster sessions/intervention delivered over an extended period to ensure incorporation of healthy living into the individual’s lifestyle
In summary, the draft healthy-living intervention that we developed was to be delivered in eight individual sessions over a 12-month period by a STR worker specially trained for this purpose. To promote consistency we produced a manual, outlining the content and key activities to be followed in each session. In addition to individual sessions, optional active group sessions were offered to encourage people to make healthy-lifestyle changes. The intervention was culturally adapted to meet the needs of young people from the South Asian community and strategies for behaviour change are underpinned by the principles of the common sense model. Information about healthy living, including a range of healthy recipes, was provided for participants in a booklet.

Stakeholder consultation
The final stage of the development work involved presenting the draft intervention to a range of stakeholders including service users (n = 3), carers (n = 2) and professionals (n = 3) to elicit their views regarding its acceptability and to gather suggestions for the group activities and the duration of the intervention. There was agreement that the intervention was both acceptable and feasible. Two key suggestions emerged: (1) to develop a website that had similar intervention to the healthy-living book and (2) that we should involve service users in the running of the groups.

Following the stakeholder consultation we started to develop materials to support the delivery of our intervention. These included a training manual for the STR workers who would deliver the intervention, a healthy-living booklet for participants in the study and a website (see www.helper-interact.co.uk/: website active at time of writing). We also recruited four service users who were interested in running groups for the study and organised a workshop to train both the STR workers to deliver the individual intervention and the service users to support the STR workers when delivering group activities.

The healthy-living intervention
The healthy-living intervention included eight individual sessions over a 12-month period with an emphasis on facilitating participatory exercise and dietary change through the development and implementation of patient-led action plans. These sessions were delivered by a STR worker trained in the delivery of the intervention. To facilitate implementation of exercise and dietary change a range of optional active group sessions was offered by the STR worker for those who prefer a group-based activity. To optimise engagement, choice and self-management, a booklet was given to all participants providing educational advice, action plans, goals, details of the group sessions, healthy-eating recipes on a budget, etc. (see Appendix 3). A strong emphasis was placed on maximising carer/family engagement.

Individual sessions
The intervention comprised eight individual sessions, five in the first 3 months followed by two in months 4–6 and a final session in months 7–12 to ensure that gains were incorporated into the individual’s lifestyle. The decision to include eight individual sessions was based on recommendations given during the synthesis day event, as there were no data to suggest an appropriate number of sessions (see Table 5). In brief, sessions one and two focused on eliciting health beliefs and developing a collaborative individualised action plan and goals for change. Such goals took account of previously and currently enjoyed activities that were exercise related. Sessions three to five focused on the implementation of the action plan (and, when agreed, the inclusion of family/carer involvement). Collaborative problem-solving identified and facilitated solutions to barriers to implementing the action plan. STR workers accompanied clients to particular activities (gym, swimming, etc.) to maximise implementation. Sessions six and seven focused on progress and monitoring of the goals and action plan and adaptions made as necessary. Session eight focused on working with the user to try to ensure that implementation is embedded within his or her everyday routine.

Group sessions
In addition to the individual sessions a range of optional group sessions, some of which were already being delivered by the early-intervention service teams (e.g. football, cycling), was delivered by STR workers, who also set up a range of group sessions including walking and cycling groups.
The healthy-living intervention booklet

A healthy-living intervention booklet was given to all participants and provided accurate information about healthy living, including government guidelines on exercise and diet; strategies for implementing such changes into usual daily routines; culturally varied recipes; barriers to and facilitators of implementing healthy living that are specific to the participants’ mental health problems, including fatigue and motivation; a section for families and carers; and information on local activities. Following the suggestion from the stakeholder group during the development work, a website was commissioned and developed by a service user (see www.helper-interact.co.uk/).

Training

Training was provided by the trial team to three STR workers and four service users and consisted of a 3-day intensive training programme. The training was accompanied by a training handbook that included detailed session-by-session outlines (see Appendix 4). The training focused on all aspects of delivering the intervention from initial assessment to elicitiation of health beliefs, developing collaborative action plans and goals, engaging family/carers, monitoring and collaborative problem-solving and overcoming barriers to implementation and running groups. A significant portion of the training was spent practising the above skills using fictitious but typical cases to enhance learning and skill. Because of staff turnover the training was repeated on two occasions.

Supervision

Clinical supervision for the STR workers was provided on a 2-weekly basis by a member of the trial team.

Phase 2: evaluation of a healthy-living intervention to control weight in people taking antipsychotic medication after a first episode of psychosis

In phase 2 we aimed to determine the uptake, adherence and clinical effectiveness of a healthy living intervention designed to reduce weight gain. We conducted an exploratory RCT, comparing the intervention with treatment as usual in two early intervention services for psychosis in England. Evidence from this phase has been published elsewhere.92

A summary of the work is described below.

Aims and objectives

Our overall aim was to determine the feasibility, acceptability and effectiveness of our developed health living intervention utilising an exploratory RCT.

Objectives

1. To estimate the effect size of a healthy intervention by comparing outcomes between:
   i. individuals receiving the intervention with treatment as usual
   ii. the subgroup of the intervention arm prescribed olanzapine or clozapine at randomisation compared with the remainder of the intervention group.

2. To examine recruitment rates, uptake and adherence to the intervention.

3. To determine the direct costs associated with the intervention.
Methods

Design
An exploratory single blind RCT using a parallel group design to compare a healthy living intervention plus TAU with TAU only.

Participants
Current users of early intervention services in the north-west of England experiencing a first episode of psychosis in the preceding 3 years with a BMI of ≥ 25 kg/m², or ≥ 24 kg/m² for individuals from the South Asian community.92

Procedure
Case managers screened their personal caseloads to identify service users meeting study criteria. All potentially eligible individuals were provided with a study information sheet. Those service users consenting to be contacted were contacted by a researcher and offered an appointment to assess their eligibility. Randomisation of eligible individuals entering the trial was undertaken by an electronic software program (Open Source Clinical Data Management System: OpenCDMS, University of Manchester, Manchester, UK, www.opencdms.org) and stratified by whether or not the individual had commenced olanzapine or clozapine medication in the preceding 6 months. Randomisation outcomes were concealed from the researchers (who remained blind when undertaking assessments) but were communicated to the trial manager, who notified the STR worker if allocated to treatment. Researchers reported unblindings if these occurred during the follow-up assessments conducted at 6 and 12 months.

Interventions

Healthy-living intervention
Full details of the development of the healthy-living intervention are reported elsewhere.93 The format of the intervention constituted eight individual sessions with a support time recovery worker (who had undertaken a 3-day intervention training course), across a 1-year period and supported by an accompanying intervention manual/website. The content of the individual sessions involved the elicitation of existing health beliefs, psychoeducation, the development of personalised goals/action plans and an ongoing review of goal achievement progress. These sessions were supplemented by optional STR worker-supported group activities such as cycling and cooking.

Treatment as usual
Individualised case management in the early intervention service and enhanced care planning.

Measures
The primary outcome was BMI. Secondary outcomes included physical activity levels, depression, diet, quality of life, medication usage, health status and health economics. Assessments were conducted at baseline, 6-month and 12-month follow-up. (For full details, see Lovell et al.92)

Results
A total of 971 participants were caseload screened (for flow diagram see figure 1 in Lovell et al.92). Potentially eligible participants providing consent to be contacted were approached by the researcher (n = 148), of whom 105 individuals providing consent and meeting eligibility criteria were randomised. Of the 54 individuals randomised to the intervention (51 to TAU), five withdrew. The follow-up completion rate at 12 months was 88.6%.

Results found no significant effects between the intervention and TAU group. However, the effect of the intervention was larger (effect size 0.54, not significant) in 15 (28%) intervention and 10 (20%) TAU participants who were taking olanzapine or clozapine at randomisation.
Discussion
We found that our healthy-living intervention had a small but non-significant reduction in BMI compared with TAU. We found that in those participants who were taking olanzapine or clozapine at randomisation, there was a larger but non-significant effect. We successfully recruited to target and achieved an 89% retention rate at 12-month follow-up rate. Of the intervention participants, 78% completed 6–8 sessions. Overall costs of health and social care services used were lower but not statistically significant in the intervention group, compared with the TAU group.

Qualitative acceptability interviews
Aim
The aim of the qualitative acceptability interviews was to explore the acceptability of the healthy-living intervention from the perspective of those receiving the intervention.

Methods
To explore acceptability from the patients’ perspective, all patients randomised into the intervention arm were asked to participate in an interview to ensure inclusion of a range of patient baseline characteristics (i.e. age, gender and ethnicity to ensure a diversity of views). Semistructured interviews with consenting participants were conducted by a researcher. An interview guide (see Appendix 5) was developed by the trial team to ensure exploration of key areas including timing, content and duration of the intervention, STR workers’ qualities and barriers to and facilitators of the intervention.

Analysis
For acceptability the tapes were transcribed verbatim. Data were analysed using a framework analysis,94 as described in the section on interviews with service users/health professionals.

Results
Of the 49 participants randomised to the intervention, 25 were included in the acceptability study. The age range of participants was 17–39 years (SD 5.72 years) and 15 were male. Recorded interviews were of 24–64 minutes’ duration (mean 41.4 minutes). Participants who participated in the acceptability interview undertook a significantly greater number of intervention sessions (mean 7.3 sessions, SD 1.2 sessions) than those who did not (mean 5.8 sessions, SD 2.6 sessions). However, there was no significant difference in BMI at 12 months’ follow-up between those who did and those who did not take part in the acceptability interview.

Two main themes emerged from the analysis: (1) views on the delivery method and (2) the STR worker.

Views on the delivery method
Personalised goals and action plan Participants felt that they had worked collaboratively with their STR worker to set individualised and achievable goals and associated action plans. Goal-setting appeared to be viewed positively as a tool to motivate behaviour change:

Once you reach the 3-month goal, it gives you this spur to go for the 6 months.

Pt.8, M

The content, adequacy and format of the healthy-living education provided The healthy-living education provided was widely regarded as helpful by participants regardless of their level of pre-existing knowledge, serving either as a first introduction to how to live healthily or as a useful ‘refresher’. Participants largely appreciated the written materials provided (e.g. the booklet) because they could be quickly accessed. However, some struggled to make use of such materials because of a dislike of reading or because of literacy problems; these individuals felt that the intervention could be improved through an option for more practical forms of learning (e.g. cookery courses) or by offering the information on a DVD.
The trial website was poorly utilised but it was unclear whether this was because of a lack of acceptability or because of participants not having been made aware of it.

**Views on group activities** Service users’ willingness to join in with group activities was mixed; whereas some found group activities helpful, others declined the offer, suggesting that group activities could be stigmatising or could compromise confidentiality. Those valuing group activities often emphasised the social benefits, such as making friends and improving social skills.

**Joint activities with the support, time and recovery worker** Undertaking joint sports activities with the STR worker provided a confidence boost and/or motivation to try physical activities that participants would have felt unable to attempt alone. For example, one individual who suffered from agoraphobia progressed from walking around the ‘block’ with his STR worker to joining a local walking group. Some individuals wanted further opportunities to undertake joint activities with their STR worker and a small number reported disappointment that they had not received the opportunity to do this.

**Tools to monitor progress** Monitoring tools such as food diaries and goal progress ratings were regarded as motivational and educational. One individual was able to re-evaluate the cause of her weight gain after completing a food diary:

> When I wrote down the diary – this is one of the ideas – of what I was eating I realised it was what I was eating that was making my weight go up and not just taking the pills.

Pt.3, F

Participants found the experience of being weighed as part of the study follow-up procedures helpful, often because they did not have access to good-quality scales at home.

**The format of the intervention** Service users largely felt that the length and spacing of sessions was appropriate, with only a small number expressing a preference for a longer or more intense intervention. Home visits from the STR (as opposed to meetings at a clinic, etc.) helped participants to fit the sessions into their daily routine.

**The support, time and recovery worker**

**Tailoring to the individual** Participants described an individualised intervention into which they could have significant input, for example goal-setting, the pace of lifestyle changes and choice of activities. Delivery of a tailored intervention appeared to be related to the STR workers’ ability to listen and respond to individual needs and preferences:

> It was nice because it was just someone supporting you with what you wanted to do rather than supporting you with what someone else told you to.

Pt.2, M

The small number of individuals who were less positive about the intervention appeared to have received a less individualised intervention. For example, one individual felt that his STR worker had failed to get to know him, with the consequence that she had tried to motivate him to undertake sports activities that he disliked.

**Quality of the relationship** The quality of the relationship with the STR worker appeared to be a key factor in the engagement of participants in the intervention. It was clear that many participants liked and enjoyed meeting their worker:

> I saw [him/her], like someone nice, like, a friend I would see now and again.

Pt.23, F
Participants appreciated the flexible, understanding and non-judgemental attitude of their STR worker and often felt that they shared common ground, helping to put them at ease. One individual spoke positively about being able to cancel intervention sessions without fear of a negative response:

[Heshe] understood where I was coming from. And I never felt . . . it wasn’t like phoning me doctor or perhaps, you know when I used to work, like phoning my boss and saying, ‘Oh, I can’t come in’; I never felt that intimidation.

Pt.9, M

Conclusions

- Goal-setting was a helpful tool, facilitating positive lifestyle changes.
- Although extremely useful for some, written materials may not suit all learning styles. An educational DVD or a practical course may provide an accessible alternative.
- Although some individuals find group physical activities motivational, others regard them negatively, for example finding that they lack confidentiality. One-to-one joint sports activities appear to be more widely acceptable.
- Written monitoring tools can help individuals to re-evaluate their behaviours and motivate positive changes to their lifestyle. Future interventions could include weight monitoring within the intervention package.
- Home visits were convenient for participants. Eight sessions were largely felt to be appropriate; however, a minority of individuals would have preferred a more intensive intervention.
- The key to the intervention appeared to be related to the STR workers’ ability to build high-quality relationships with service users by being flexible and non-judgemental and by recognising and responding to the individual needs and preferences of participants.

Overall conclusions of the workstream

- Evidence is accumulating that weight gain is a serious problem for people with psychosis, leading to cardiometabolic problems and early death, and it is increasingly recognised that this must be addressed.
- We used information drawn from a variety of sources (a systematic review and interviews with service users, case managers and key stakeholders) to design a theory-based intervention specifically for people with recent-onset psychosis.
- In an exploratory trial of the intervention, we were able to train STR workers to deliver the intervention, to recruit to target, to retain participants and to achieve a high rate of follow-up and the intervention was acceptable to participants.
- The effect of the intervention on reducing weight or controlling weight gain was small and not statistically significant, although it could be argued that we set ourselves too difficult a task by focusing on people at particular risk of weight gain (those with recent-onset psychosis) who were already overweight or obese.
- In the subgroup taking two particular antipsychotic medications, olanzapine and clozapine, the effect of our intervention on reducing weight was larger, suggesting that future work should focus attention on this subgroup of service users.
Chapter 3 Substance misuse workstream: the Asking about Substance use and Psychosis – Ideas, Reactions and Experiences (ASPIRE) study and the Rethinking Choices After Psychosis (ReCAP) randomised controlled trial


Abstract

Objectives: To optimise and evaluate integrated motivational interviewing and cognitive–behavioural therapy (MiCBT) for substance misuse.

Methods: Qualitative interviews were conducted with 19 young people with recent-onset psychosis to identify factors influencing the use of substances. Themes were used to inform the development of a phase-specific MiCBT intervention focused on harm reduction for young people with psychosis. The intervention was evaluated in a pragmatic single-blind randomised controlled trial (RCT) in which 110 participants were randomly allocated to one of three conditions: a brief MiCBT intervention (up to 12 sessions over 4.5 months) with standard care from an early-intervention service; a long MiCBT intervention (up to 24 sessions over 9 months) with standard care; or standard care alone. The primary outcome was change in cannabis use as measured by the timeline follow-back (TLFB).

Results: Thematic analysis of the transcripts from the qualitative interviews identified four key themes: influence of perceived norms on behaviour; attributions for initial and ongoing drug-taking behaviour; changes in life goals affecting drug use; and beliefs about the links between mental health and drug use. The outcomes of the RCT are not yet available but data indicate good retention and engagement rates: the majority of participants (n = 60, 80%) engaged with the therapy and we retained 76 (69%) participants until the end of the trial.

Conclusion: This is a methodologically robust study that will produce results that are generalisable to mental health services.

Introduction

Large numbers of people with psychosis use substances. Cannabis is the most widely used drug, with particularly high prevalence rates in people experiencing their first episode of psychosis. There is evidence that cannabis use is associated with worse individual outcomes and with greater societal costs. Negative consequences of use include more suicidal behaviour, violence, social instability, non-adherence with treatment, service disengagement and an increased likelihood of relapse and hospitalisation. For young people who experience psychosis, continued cannabis use can exacerbate the symptoms of psychosis and may maintain and aggravate the disorder. Furthermore, these risks are present even at levels of consumption that would be considered unremarkable in the general population, suggesting that psychosis brings an increased sensitivity to cannabis.
It is widely believed that the pattern of illness established during the ‘critical period’ after a first episode determines the long-term prognosis of the condition.\textsuperscript{103} Thus, repeated psychotic episodes associated with cannabis use may increase the risk of treatment-resistant symptoms and precipitate an irreversible decline in social functioning, leading to lifelong reliance on health and welfare services. Hence there is a strong case for targeting people at an earlier stage of the illness when patterns of cannabis use are not so well established\textsuperscript{78} and any deterioration associated with prolonged use has not set in. Additionally, there are some indications that it may be easier to motivate patients to reduce cannabis use if intervention occurs at an early stage of the psychosis. For example, in Melbourne, Australia, it has been reported that 50\% of young people using cannabis at admission to early-intervention services voluntarily cease use within the first 6–10 weeks.\textsuperscript{104}

Although the negative consequences of cannabis use are well documented, there are very few interventions of proven efficacy for people who use cannabis and have psychosis. A Cochrane review of psychosocial interventions for people with substance misuse and severe mental illness\textsuperscript{105} found ‘no compelling evidence to support any one psychosocial treatment over another to reduce substance use (or improve mental state) by people with serious mental illnesses’ (p. 3), although the review did note some support for integrated MiCBT based on pilot work.

To date, four RCTs have evaluated interventions aimed at reducing cannabis use in young people with recent-onset psychosis,\textsuperscript{106–109} all of them small (sample sizes ranging from 47 to 103) and with intervention periods ranging from 3 to 6 months. One intervention utilised motivational interviewing (MI) only\textsuperscript{107} and the rest combined MI and CBT, one as a group intervention.\textsuperscript{109} None of the studies investigating integrated MiCBT found an advantage of MiCBT over the control conditions in terms of reducing cannabis use or improving clinical outcomes, although in one study the treatment group reported better quality of life post treatment.\textsuperscript{109} In the MI-only study\textsuperscript{107} there was a modest post-treatment reduction in number of joints smoked per week but this was not maintained at 12 months’ follow-up.

To take forward this area of research we optimised MiCBT to make it phase specific to the ‘critical period’ of early psychosis, developed phase-appropriate accompanying psychoeducational materials and designed a RCT to evaluate the intervention. Our aims were to compare a long-term intervention (24 sessions delivered over 9 months) with a brief intervention (12 sessions delivered over 4.5 months), both aimed at reducing cannabis use in a sample of people with recent-onset psychosis, and to examine the impact of the interventions on a range of clinical outcomes. Each intervention had the same focus: increasing motivation to reduce or to be abstinent from problematic cannabis use and planning, implementing and consolidating change. Thus, there were no differences between the two approaches other than the number of sessions scheduled and the time available to achieve each stage of therapy.

We recognised that to optimise MiCBT a greater understanding of the psychological factors that influence the use of substances was necessary, in particular an understanding of the self-reported reasons for initiating, continuing and stopping substance use in young people with psychosis. Previous investigations have involved people with more established psychosis, have been largely questionnaire based and have focused more narrowly on self-reported reasons for substance use.\textsuperscript{110–112} There is evidence that patterns of, and motivations for, substance misuse may differ during first-episode psychosis.\textsuperscript{113} We therefore conducted an in-depth qualitative investigation of experiences of substance use in young people with psychosis.

Our hypotheses were as follows:

1. Some young people who have used substances before or during the first episode will discontinue spontaneously for reasons that can inform the development a phase-specific psychological intervention.
2. The MiCBT intervention will be efficacious in reducing substance use in people with early psychosis.
3. A brief version of the MiCBT intervention (12 sessions) will be as efficacious as a longer version (24 sessions).
Phase 1: Asking about Substance use and Psychosis: Ideas, Reactions and Experiences (ASPIRE) – a qualitative investigation of the reasons why young people continue/discontinue using substances following psychosis

Introduction
In this stage of the research we aimed to access the psychological factors associated with substance use in first-episode psychosis, specifically the factors that enable or present barriers to stopping using substances. We investigated reasons for substance use; why people stop or do not stop using substances; and why some people start to use substances again following a period of abstinence. The exploratory nature of this work made a qualitative design ideal. We chose the grounded theory approach as our aim was to generate or discover a theory of substance use in first-episode psychosis. Our ultimate aim was to use the theory generated from this qualitative enquiry to aid in the development of a phase-specific intervention for substance use in early psychosis.

Methods
Participants were recruited from an early-intervention service based in the north-west of England between January and September 2008. Purposive sampling was used to achieve variation in age, gender and ethnic background to ensure that the sample would reflect the whole service population. Inclusion criteria were:

- acceptance into the early-intervention service for treatment of psychosis (i.e. not including patients from the ‘high-risk’ group)
- a period of 3 months when the client used substances on at least 2 days of each week for half of the weeks in the 3-month period. This 3-month period will be either at present or in the past, as far back as 6 months before the first contact with the early-intervention service
- working knowledge of the English language
- aged > 16 years.

Participant eligibility was checked using a substance use checklist that detailed use of substances (amount and frequency of use) over the preceding 3 months and the substance use modules of the Structured Clinical Interview for DSM-IV Axis 1 Disorders (SCID). Interviews took place once eligibility was confirmed and informed consent obtained. Interviews were conducted at a place chosen by the participant, typically their own home. The main interview was topic guided (see Appendix 6) and lasted between 60 and 90 minutes. The study followed an iterative approach with the topic guide developing as the study progressed to reflect the developing inductive theories. This practice is in line with a grounded theory approach. All interviews were digitally recorded and transcribed verbatim.

Analysis
The qualitative data were analysed by a team comprising two academic researchers, three clinical academics with psychological perspectives, one specialist nurse therapist and a non-clinical academic with expertise in qualitative methodology. One member of this analysis team had previous experience of using mental health services and of substance misuse.

Interview transcripts were read and preliminary coding was conducted concurrently with data collection. To ensure transparency and reliability, all transcripts were read and analysed by the interviewer and coded by at least two members of the team. The analysis process was managed using NVivo software (version 9; QSR International, Warrington, UK). Team members discussed coding and their interpretation of the transcripts in detail to refine codes and identify key themes emerging from the data. The original transcripts were then reread, coded and indexed. The themes highlight that which is shared by interviewees, but we have also acknowledged data that are at odds with these themes. The team
approach to analysis allowed inconsistencies between the data and themes to be debated, refined and reflected in the final presentation of the main themes.

Results

Participants

Nineteen participants were interviewed and their interviews were transcribed and labelled A–S to preserve participant anonymity. All participants had experienced a psychotic episode and were within 3 years of first contact with the early-intervention service. Ten participants (53%) reported currently misusing substances at the time of the interview and the remaining nine (47%) reported recent use. All participants currently were or had previously been regular cannabis users and for 13 (68%) cannabis was the primary drug of use. Eleven participants (58%) were regular users of more than one substance. Other drugs commonly used were amphetamine, cocaine, ecstasy, heroin, methadone and diazepam. The median age of participants was 23 years (range 18–35 years) and the majority (n = 15, 79%) were male and described themselves as white British (n = 17, 89%). Twelve participants were unemployed (63%) and two (11%) were students. The gender and ethnic mix of the sample are representative of the larger population of young people in the early-intervention service from whom they were recruited, which is predominantly white British and has a ratio of males to females of > 2 : 1.

Key themes

Analysis identified four key themes in participants’ accounts of factors influencing their substance abuse:

1. the influence of perceived drug norms on behaviour
2. attributions for initial and ongoing drug-taking behaviour
3. changes in life goals affecting drug use
4. beliefs about the links between mental health and drug use.

Theme 1: the influence of perceived drug norms on behaviour

When participants were questioned about how they began using drugs they often talked about how ‘normal’ drug taking was in their neighbourhood or community. Drug taking was often described as an integral part of local landscapes. For example, one participant (M) reported that ‘everybody I know takes drugs’. Another (E) stated that:

Cannabis is probably used even more than people even think it is, it’s like there’s so much that I’ve witnessed that only in a small town like [university town] and like where I’m from and stuff, but it, it just makes me feel that it’s everywhere in this country.

Participants who contributed to this theme perceived little stigma attached to drug taking. They saw drug use as a commonplace and socially acceptable behaviour in their communities. For some participants, drug taking was about subverting perceived social norms rather than being part of ‘normal’ culture. They believed that drug taking offered them a way out of ‘normative worlds’ and into a more exciting life. As participant A stated:

I’d rather live this life than **** do nothing all my life, to be honest. At least I’ve done sommat.

Some drugs were perceived as being more acceptable than others. One amphetamine user (R) explained:

Heroin’s always seemed to me as a really dark evil drug that made people, what I call wrong people, you know thieve them, do anything basically to get more heroin, even if they had to kill and stuff.
Other drugs, particularly cannabis, were perceived as being likely to improve social behaviour. Participant A reported:

> It [cannabis] keeps us out of trouble to be honest and that’s what it used to do when we were younger as well, I mean, it stops you from going out and doing, causing riots basically or you go into like a bus shelter and you’d have a smoke there or sommat.

It was apparent that there was a tension between the acceptability of personal drug use and the morality of promoting drug use to family or friends. Participants generally agreed that it was wrong to encourage other people to take drugs and that drug use was not an activity they would like to see their own family, particularly their children, engage in.

**Theme 2: attributions for initial and ongoing drug-taking behaviour**

Some, but not all, participants identified specific reasons for their drug use. Among those who were able to identify specific reasons there were two types of attribution: internal attributions (i.e. that drug and/or alcohol use was an active personal choice) and external attributions (i.e. that substance use was due to the influence of others). Those people who made internal attributions described seeking out information and weighing up the pros and cons to make their decisions, summed up by participant J as:

> No one told me I should do this, I’ve never had drugs pushed on me . . . I’ve always knowingly gone into it, but erm, essentially it’s fun, it’s a **** great time sometimes.

In brief, this group found substance use to be ‘fun’. They also reported beneficial effects of substance use on interpersonal relationships, using drugs as a way of connecting with other people and fitting in, both by reducing anxiety and improving social performance. As participant I explained:

> I never liked being normal from the age of 12, I’d rather be drunk, you know it were drink at first, and erm, I used to get drunk at first, to become a louder person, ‘cause I were always a quiet, and speed makes you not quiet and it gives you confidence and all that, all things that I needed really, or that I thought I needed, ‘cause I weren’t a confident person so I, yeah it were probably to give me the confidence to talk to other people and have fun.

For those who attributed substance use to external factors, some described being coerced into it by other people whereas others described a more passive course, with substance use initiated and maintained because of exposure to substances as part of a social network.

**Theme 3: changes in life goals affecting drug use**

In many accounts a key reason for reducing or stopping substance misuse was a change in personal life goals, especially an increase in the perceived value of health, disposable income and close family relationships. These reasons were largely identified by older participants who had reduced their use of substances and who were reflecting on the reasons for this. For example, one participant (J) said:

> I don’t believe that I could possibly cope with my job and my relationships and so on and I don’t want to risk them, and so I don’t do it any more. I want to erm, make new circles of friends and I’d rather go to dinner parties these days than to a rave, you know, I’d like to have a nice steak dinner in a restaurant more than I’d like to take a pill.

Younger participants who were still using drugs identified their current goals and existing social networks as barriers to changing their drug use, recognising that drastic changes to these would be needed to allow them to make changes, as the following exchange shows:

> Participant N: All my friends do it, they all take drugs, they all smoke weed and not one of them has ever thought of quitting or even if they have they’ve not a chance they ever will, same for me.
Interviewer: So you don’t think you could actually do it?

Participant N: I’d need to be taken away, like erm, you could put me in a hospital say for 2 weeks, I’d need to go away for a month, where I can’t get hold of any, you know, I can’t go out and get it or touch it, basically cold turkey, ’cause if I’m around it and around people I can’t say no.

Some participants did experience significant life events that led to sudden and dramatic changes in behaviour. One participant described how family members intervened and took away his daughter:

Me mum and dad took me daughter off me, fetched her back here and they said I had a choice of staying with [ex-partner] and staying on the drugs, or coming home, getting myself ok clean and having me life with me daughter, so I decided to move out, get meself clean and sort meself out.

**Theme 4: beliefs about the links between mental health and drug use**

Many participants had theories about the connection between drugs and the onset of psychosis that were clearly influencing their behaviour. Some drew on sophisticated formulations in which drug use mediated between biological and/or life events and the onset of mental health problems, whereas others reported substance use to be a way of coping with existing mental health problems such as anxiety and depression. At the same time there was awareness that drug use could exacerbate symptoms and make problems worse. As participant S reported:

It just helps to bury your problems just for that day and then, but you don’t realise that your problems just stay there that are waiting for you to come back out again, they don’t just like disappear when you want them to, that’s all I would say with drugs, just buries it for you a couple of days, a couple of hours or what have you, and then it just comes back, it just keeps on building and building, adding more problems to it, you just keep on building it up to the day it just erupts.

The themes that emerged from this work develop our understanding of patterns of drug use in people with early psychosis and can be used to inform interventions at a number of levels. The changes in life goals that are associated with changes in substance-use behaviour lend support to the use of harm reduction approaches. Findings support the use of psychological approaches that help people to identify and acknowledge the positive reasons for their drug use, to explore the potential negative effects, including the impact on mental health problems and to find alternative strategies to achieve desired goals. In particular, the importance of peer group identity needs to be acknowledged and the role of drug use in facilitating inclusion into a desired social group needs to be examined. Finally, educational materials are unlikely to be helpful unless they resonate with personal experience and are offered in forms and via media that appeal to this age group.

**Development of the intervention**

The intervention that we sought to optimise and evaluate was originally developed for use in the Motivational Interventions for Drugs and Alcohol misuse in Schizophrenia (MIDAS) trial. The MIDAS trial included people with substance use of any type (including use of alcohol above safe limits) who had established psychosis (i.e. who were not experiencing their first episode of psychosis) and the intervention was, therefore, adapted to be relevant for a first-episode population with cannabis use as its main focus. The intervention integrates the recognised therapeutic approaches of MI, CBT and relapse prevention. MI was included because it helps people to recognise the advantages and disadvantages of substance use, including the role of substances in psychotic experiences; it places responsibility for changes in behaviour on the individual, while encouraging the therapist to elicit and reinforce the person’s motivation for change until they reach an action stage of planned substance reduction. CBT helps the person plan and achieve change, including, when appropriate, helping him or her to understand his or her psychotic experiences, and it offers alternative strategies for managing symptoms that can take the place of substance misuse. Relapse prevention identifies the obstacles that arise in managing problematic substance use behaviours, reviews the factors that may trigger relapse of problematic substance use at different
stages of recovery and presents procedures for teaching effective cognitive and behavioural coping strategies to deal with problematic substance use. The benefit of integrating MI, CBT and relapse prevention is in ensuring that all elements of the service user’s problems are given attention and that any negative interactions between mental health and substance-use problems can be formulated and addressed while taking into account the person’s motivation to address or reduce his or her substance use. We expected that in some participants motivation to reduce substance use would be low, and MiCBT, with its formulation-driven approach, is sufficiently flexible to work with other client-led problems if the initial attempts to increase the client’s motivation for change in substance use are unsuccessful.

The therapeutic model

The heuristic model underpinning the intervention (Figure 7) was also developed for use in the MIDAS trial. The model combines aspects of Marlatt and Gordon’s social cognitive theory of problematic substance use\(^{119}\) with elements of Blanchard and colleagues’ affect regulation model.\(^{120}\) The model, shown here as applicable to people with co-occurring psychosis and cannabis use, proposes that certain situations and cues trigger cannabis use-related thoughts, which, in the absence of alternative strategies and in the context of low self-efficacy for resisting use and positive expectancies from use, make the person vulnerable and more likely to use cannabis. This interaction between situations and cognitive/emotional reactions becomes the basis of a repeated cycle that maintains the cannabis use.

Within this context, poor problem-solving abilities and limitations in obtaining pleasure in ways other than through cannabis use increase the likelihood of the learned expectations of the positive benefits of repeated cannabis use being reinforced. We have found in clinical practice that the contributing role of cannabis use to psychosis may not be as significant to the individual as to other concerned people, that is family or mental health services. Rather, cannabis use is likely to be associated with more positive than negative expectancies, leading to a situation in which cannabis use is maintained. Such perceived positive benefits may include, for example, mood enhancement, relief from boredom, anxiety reduction, opportunities for social interaction with other cannabis users, ‘time out’ from problems, the blocking out of unpleasant thoughts, general feelings of well-being, release from unpleasant self-consciousness and performance enhancement through physiological effects on arousal or other mechanisms.

Using the model as a template facilitates the therapist in completing a detailed functional analysis of the links between the person’s psychosis, associated difficulties and continued cannabis use. To achieve this, the therapist elicits information at distinct stages of the therapeutic intervention. The model assists the therapist to elicit self-motivational statements from the individual regarding the negative aspects of continued substance use and to then feed this back through a shared understanding.

![Figure 7: The therapeutic model.](image-url)
The intervention

We recognised the need for therapy to explore and resolve ambivalence before engaging in change strategies. As such, the therapy has three specific phases: (1) building engagement; (2) exploring and resolving ambivalence in the direction of changing problematic cannabis use; and (3) the use of recognised psychological intervention strategies to facilitate changing problematic cannabis use in the context of psychosis (Table 6). Each phase of therapy comprises therapeutic strategies (stages) specific to that particular phase. The accompanying manual (available from Professor Christine Barrowclough on request) describes how to deliver therapy appropriate to individual need. For example, the service user who identifies early in therapy, that is in sessions 1–4, that he or she wants to commit to making a change in his or her cannabis use would not need to focus on phase 2 strategies designed to explore and resolve ambivalence. The service user who is engaged in therapy but who remains ambivalent about changing his or her cannabis use, however, will continue to be engaged in phase 2 strategies designed to explore his or her ambivalence.

We optimised the intervention used in the MIDAS trial by making it phase specific for the ‘critical period’ of early psychosis, in which the patterns of, and motivations for, substance misuse appear to differ from those seen in the later stages. In a first-episode population, the prevalence of street drug use is high and our qualitative work confirmed that issues such as drug use being perceived as a normalising social behaviour would have to be addressed. We used the findings from the qualitative study to develop appropriate and youth-friendly information resources suitable for this population, using materials from early-intervention services in other countries as a starting point.

In the MIDAS trial we found that people who made changes during therapy were more likely to maintain this change at follow-up. We therefore adapted the intervention to include greater use of behavioural experiments (experimenting with making changes) earlier in the therapy. For those not committed to making change, the behavioural experiments were an opportunity to test out their positive cannabis beliefs, for example ‘If I don’t use cannabis until 8.00 pm rather than when I wake up (11.00 am) I will not be able to manage my anxieties’. Belief ratings were elicited both before and after the experiments. Ways of managing the situation differently during the experiments were discussed. Conclusions from the experiments were discussed with the aim being to explore positive expectancies of cannabis use.

Our qualitative work showed that some young people with psychosis are ambivalent about any potential negative consequences to their mental health as a consequence of their cannabis use. They may associate a number of positive expectancies with cannabis use such as aiding sleep, reducing anxiety and fitting in with others socially. Furthermore, cannabis use might be a significant aspect of their social identity given its extensive use within the social network.

We recognised that service users with early psychosis are typically young people entering mental health services for the first time. They come into early-intervention services with a variety of expectations, previous experience and information. Many may not necessarily be actively seeking help. We therefore expected that in some cases service users may be reluctant to participate in a dialogue with the therapist about their concerns or even tolerate the presence of the therapist for periods of time.

The aims of the first phase of MiCBT are therefore to engage the service user in the therapeutic process, begin a discussion of their understanding of psychosis and cannabis use and identify their key values and goals. Several potential barriers to engagement exist in this group. Their relatively young age may impact on their readiness to engage. They may be unfamiliar with talking openly with somebody older or seemingly in a position of authority, resulting in caution or fear about discussing personal matters. There may be a perception that the therapist disapproves of their substance use and they may mistakenly believe that the point of therapy is to persuade them to give up smoking cannabis completely. The therapy, therefore, explores these perceptions in the early engagement stage to decrease resistance and prevent early termination of therapy.
### TABLE 6 Stages of therapy

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Engagement</th>
<th>Goals</th>
</tr>
</thead>
</table>
| Stage 1 | Building engagement | • Establish atmosphere of trust  
• Facilitate regular contact  
• Explore any ambivalence about therapy  
• Identify potential barriers to engagement |
| Stage 2 | Eliciting an explanatory model of psychosis and cannabis use | • Elicit an understanding of current situation with regard to onset, symptoms and consequences of psychosis  
• Elicit understanding of the interaction between cannabis use and psychosis  
• Development of therapeutic alliance in which psychosis and cannabis use can be discussed openly |
| Stage 3 | Identifying key values and development of list of goals | • Identify key values  
• Development of list of goals  
• Identify any discrepancy between values, goals and current lifestyle |
| Stage 4 | Discussing information about psychosis and cannabis use | • Facilitate discussion about cannabis use and psychosis  
• Further develop engagement and therapeutic alliance  
• Aid the engagement process |

<table>
<thead>
<tr>
<th>Phase 2</th>
<th>Formulation</th>
<th>Goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 5</td>
<td>Exploring the relationship between the symptoms of psychosis and cannabis use</td>
<td>• Explore the relationship between the symptoms of psychosis (onset, symptoms, consequences, etc.) and cannabis use (from client’s perspective)</td>
</tr>
<tr>
<td>Stage 6</td>
<td>Identification of how problematic cannabis use fits into life concerns and satisfactions</td>
<td>• Encourage the service user to establish links, however tentative, between cannabis use and areas of life concerns</td>
</tr>
<tr>
<td>Stage 7</td>
<td>Developing a shared understanding/formulation</td>
<td>• Develop a shared understanding/formulation, linking together appropriate concerns, psychosis and cannabis use</td>
</tr>
</tbody>
</table>
| Stage 8 | Discussing and identifying possible change options | • Collaboratively agree on what needs to be worked on  
• Collaboratively agree on priorities for the future |
| Stage 9 | Revisiting the formulation and developing a change plan | • Draw together relevant and key information from therapy sessions to help bring about change  
• Develop a handover plan that integrates key information from the formulation within a plan for change |

<table>
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<tr>
<th>Phase 3</th>
<th>Action</th>
<th>Goals</th>
</tr>
</thead>
</table>
| Stage 10 | Integrated CBT for cannabis use and psychosis | • Develop alternative coping strategies for salient symptom-related experiences associated with cannabis use and psychosis  
• Build self-efficacy to promote change  
• Identify the symptoms and experiences that act as high-risk triggers for cannabis use  
• Modify underlying beliefs, thoughts and problematic coping behaviours associated with psychosis and cannabis use |
| Stage 11 | Harm-minimisation strategies | • Identify potential risks associated with cannabis use  
• Develop strategies to reduce any risk considered to be unacceptable by the service user |
| Stage 12 | CBT for distressing mental health difficulties | • Reduction of distress, enhancement of existing coping strategies and development of functional coping strategies |
| Stage 13 | Developing therapy summary | • Develop a comprehensive summary of therapy  
• Develop a plan to inform future input from the early-intervention service |
The intervention seeks to gain an understanding of how the service user believes that he or she has arrived at his or her current situation with regard to involvement with early-intervention services. Thus, there is an increased focus on the participant’s explanatory model.

As the service users will have only recently had their first episode of psychosis, they may not as yet have had the opportunity to access any psychoeducation. Eliciting their current understanding helps the therapist to know what information will be useful to discuss with them in the later stages of therapy when using psychoeducation to build motivation for change.

**Development of educational materials**

Our preliminary qualitative work highlighted the need for any psychoeducational materials to be relevant to young people and to be grounded in personal experience when possible. We produced several information leaflets to be used during therapy. These provided easily digestible information on reasons that people have given for using cannabis, measuring amounts of cannabis use in comparison to use in the general population, potential negative consequences of cannabis use and managing cannabis withdrawal (see Appendix 7).

In addition to these leaflets we developed two short animations to be watched during stage 4 of the therapy – ‘Providing and discussing information on psychosis and cannabis use’. These animations, in DVD format, were based on transcripts from the Asking about Substance use and Psychosis – Ideas, Reactions and Experiences (ASPIRE) study previously outlined and were thus aimed specifically at service users within early-intervention services who have had an episode of psychosis and who also use cannabis. The animations were developed in a user-friendly format and consist of two segments of film, each 3 minutes in length, in which two animated characters talk about their experience of cannabis use and psychosis.

The style of the animation was inspired by the Lifeline.org.uk publications developed by Mark Holland and Mike Linnel, in particular the Out of your Head guides (see www.exchangesupplies.org/shopdisp_A37.php; accessed 19 November 2014).

To develop the DVD two team members reviewed the 19 interviews transcribed for the ASPIRE study. Sentences fitting within the themes identified by ASPIRE were highlighted and extracted. From these extracts four stories were constructed and scripts developed. Our aim was for the scripts to be believable, for the characters within them to be ‘recognisable’ and for service users to be able to identify with them and with their stories.

Scripts were reviewed by a local consultant dual diagnosis nurse and other team members before being sent for animation by the graphic design team at the Media Centre at the University of Manchester. Two of the scripts were eventually animated (see Appendix 8 for a still image from the DVD) and voiceovers were recorded by actors with appropriate regional accents. Copies of the DVD are available on request from the authors.

Our plan was for the therapist and service user to watch the whole DVD or clips together to generate discussion. The DVD was also used as an aid to engagement by making a change from the usual format of talking and listening. For example, the therapist might ask, ‘In what ways do you think [the character] could improve his current situation?’ or ‘In what ways are [the character’s] experiences similar to your own?’

Following our preliminary work, which led to the optimisation of the MiCBT intervention to make it ‘phase specific’ and the development of phase-appropriate psychoeducational materials, we conducted a pragmatic trial of the intervention within early-intervention services. Our aim was to evaluate the intervention and to calculate the likely sample size required for a definitive multicentre trial.
Phase 2: a phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis: the Rethinking Choices After Psychosis (ReCAP) trial

Methods

Design
We conducted a pragmatic RCT of brief MiCBT plus standard care compared with longer-term MiCBT plus standard care and standard care alone. The trial was overseen by independent data monitoring and trial steering committees and is reported in accordance with the CONSORT guidelines for non-pharmacological trials.93 Ethical approval was obtained from the Cumbria and Lancashire B Research Ethics Committee (reference 08/H1015/82). All participants gave written informed consent before taking part.

Participants
Participants were recruited from early-intervention services in five mental health trusts in the north-west of England between January 2009 and April 2011. Inclusion criteria were current involvement with early-intervention services; age 16–35 years; meeting DSM-IV criteria for non-affective psychotic disorder,40 a DSM-IV diagnosis of cannabis dependence or abuse,40 a history of cannabis use of at least 1 day per week in at least half of the weeks in the 3 months prior to assessment; having stable accommodation (i.e. not street homeless or roofless); possessing sufficient English to reliably complete the assessments; no significant history of organic factors implicated in the aetiology of psychotic symptoms; and an ability to give informed consent.

Estimating the sample size
For the primary outcome of frequency of cannabis use, if the intervention was successful we would expect to see a clinically significant reduction equivalent to 5 days of use relative to the control group.108 Assuming a SD of 5 at baseline, a sample of 29 participants in each of the three groups was required to have a 90% chance of detecting this difference in three pairwise comparisons using a significance level of 0.05 (nQuery Advisor, 2012; Statistical Solutions, Saugus, MA, USA).

Procedure
Potential participants were identified by referral from care co-ordinators. The research team worked proactively with early-intervention services to identify services users who might be potentially eligible for the trial. This included attending team meetings to request referrals and meeting one-to-one with care co-ordinators to review their entire caseload to make sure no-one was missed. The first approach to the patient came from the care co-ordinator. After a complete description of the study had been provided to the client, giving plenty of opportunity for him or her to ask questions and go away to talk to other people about the study, written informed consent of those agreeing to participate was obtained by a trained research assistant. Diagnostic and substance use eligibility was confirmed by research assistants using the SCID.22 A substance use checklist was used to determine the frequency and amount of substance use, including alcohol use. Participants were assessed on multiple measures before randomisation to one of the three arms of the trial.

Randomisation
Random allocation to brief therapy plus standard care, long therapy plus standard care or standard care alone was performed using openCDMS, an independent remote service. Participants were randomly allocated within each of the trusts to one of the treatment arms using computer-generated randomised permuted blocks, with randomly varying block sizes of 2, 4, 6 and 8, after stratifying by variables believed to be predictive of treatment participation or outcome (e.g. gender, living with family vs. not living with family). Notification of randomisation was immediately communicated to the trial manager and trial therapists.
Intervention
The psychological therapy was integrated MiCBT, optimised for use with a first-episode cannabis-using population. Participants in the brief intervention condition were offered up to 12 sessions of MiCBT over 4.5 months; participants in the long-term intervention condition were offered up to 24 sessions over 9 months. Both interventions were delivered at the participants’ preferred location, typically their own home. Sessions were audi-taped with the participants’ consent in order to be used for the evaluation of treatment fidelity and for therapist supervision. Therapy was delivered in accordance with the treatment manual, which is available on request from Professor Christine Barrowclough.

The therapy stages have been described earlier. Both interventions progressed through the same 13 steps outlined in Table 6. However, the long intervention allowed more time to develop the change plan and particularly the use of CBT within the plan. Progress during therapy was communicated to the care co-ordinator at two liaison meetings attended by both the therapist and the participant. These took place in the middle and towards the end of therapy.

Standard care from the early-intervention services involved in the study is compliant with the Policy Implementation Guide and includes intensive case management, crisis response, behavioural family therapy and cognitive therapy for persistent symptoms.

Training and monitoring of trial therapists
The trial therapists were two nurse therapists and one clinical psychologist, all of whom had experience in conducting CBT with people with first-episode psychosis.

The following training standards were met before the therapists commenced delivery of the intervention:

1. Met minimum training standards for the practice of CBT as set out by the British Association for Behavioural and Cognitive Psychotherapies (BABCP). Full details can be found on the BABCP website (see www.babcp.org.uk; accessed 19 November 2014).
2. Completed training in MI and supervised practice of MI with at least two clients with psychosis.
3. Achieved a ‘competence’ rating for at least one therapy tape rated on the Motivational Interviewing Treatment Integrity (MITI) scale.

Treatment was assessed in supervision using recorded therapy sessions, discussion of individual cases and feedback on the use of MI using MITI ratings. Treatment fidelity was assessed by an independent rater with previous experience of delivering and assessing MI and CBT. A sample of 20 digital recordings, each from a different participant, was randomly selected from a pool of 289 recorded sessions. Fidelity was rated on the MI-CBT fidelity scale. This scale consists of 16 items rated as either ‘compliant’ or ‘not compliant’.

Assessments
All assessments were conducted by research assistants who were blind to treatment allocation, normally in the participant’s home, but occasionally at an early-intervention service venue, doctor’s surgery or community building. Before carrying out the assessments, research assistants received extensive training in conducting psychological and substance use assessments and in collecting hair samples. They were asked to record all instances of ‘unblinding’ (inadvertently becoming aware of treatment allocation) and were required to report them to the trial manager immediately. To maintain the blinding, research and therapy staff were housed in different locations, assessment and therapy data were stored separately and participants and care co-ordinators were reminded not to divulge information that might lead to the ‘unblinding’ of the research assistants. In total, 56 instances of ‘unblinding’ were recorded involving 38 different participants. For the majority of these a new ‘blind’ assessor was allocated. When this was not possible (on seven occasions) the assessment was conducted ‘unblinded’ and assessments were rated by a blind rater via digital recording.
Data on substance use, symptoms and illness history and demographic information were collected at baseline by self-report. Care co-ordinators provided additional information on substance use to corroborate these self-reports. Outcomes were assessed after completion of treatment (at 4.5 and 9 months for all groups to prevent ‘unblinding’) and 18 months after treatment allocation.

**Substance use**
The primary trial outcome was number of days abstinent from cannabis in the last 90 days as determined by the TLFB assessment.\(^{125}\)

The TLFB assessment, administered by the research assistants, uses an annotated calendar that is personalised for each participant. Significant events or regular patterns (e.g. ‘payday’) are recorded on the calendar and the calendar then serves as a memory cue for participants as they try to recall daily alcohol and drug use. For each of the 90 days the researcher records the number of drinks consumed, the quantity (in millilitres) and the strength of alcohol (which is later converted into alcohol units) and the type, amount (in grams) and cost of the drugs consumed. Participants were instructed to be as accurate as possible but when recall was difficult they were instructed to provide their best guess.

Additional substance use outcomes, also determined by the TLFB assessment, included total consumption of cannabis (in grams) over the preceding 30 days and average daily weight (in grams) of cannabis consumed per day, number of days abstinent from all substances and percentage change from baseline in amount of cannabis used. The TLFB assessment has good reliability and validity in dual-diagnosis populations.\(^{118,126,127}\) The Readiness to Change Questionnaire (RTCQ)\(^{128}\) was used to assess motivation to change substance use. The Reasons for Substance Use in Schizophrenia scale\(^{110}\) was used to examine reasons for cannabis use and the Cannabis Experiences Questionnaire\(^{129}\) and Inventory of Drug Use Consequences\(^{130}\) assessed the self-reported consequences of use.

Care co-ordinators completed a brief version of the TLFB assessment (reporting participants’ use of substances per week for the previous 13 weeks) and the Drug Use Scale of the clinician rating scales\(^{131}\) to validate participants’ self-reports. These were conducted at baseline and at 4.5, 9 and 18 months. Additionally, 29% of the participants gave hair samples, which were subsequently examined by a specialist hair analysis company (Concateno TrichoTech Ltd, Cardiff, UK) for the presence of cannabis.

**Symptoms and functioning**
The PANSS\(^{28}\) was used to assess the positive, negative and general symptoms associated with psychosis. Distress in relation to symptoms was assessed using the PSYRATS.\(^{26}\) Functioning was assessed using the Global Assessment of Functioning (GAF) scale.\(^{22}\) Anxiety was assessed using the Beck Anxiety Inventory (BAI)\(^{132}\) and insight was assessed using the Birchwood IS.\(^{32}\) Depression was examined using the CDSS,\(^{29}\) with participants also being asked to report previous instances of serious self-harm. Attitudes towards prescribed medication were assessed using the Drug Attitude Inventory (DAI),\(^{133}\) which can be used to categorise respondents as either ‘adherent’ or ‘non-adherent’ to medication.

All assessors rated 10 ‘gold standard’ video-recorded PANSS interviews before conducting trial assessments. Mean intraclass correlation coefficients were high, indicating excellent inter-rater reliability (positive subscale 0.87; negative subscale 0.86; general subscale 0.87; total 0.89; global assessment of functioning 0.94). Ratings were monitored throughout the trial as part of supervision and intraclass correlation coefficients remained high (positive subscale 0.90; negative subscale 0.85; general subscale 0.90; total 0.95).

**Relapse and hospitalisation**
Data on relapses and hospitalisations were obtained from participant psychiatric case notes. The frequency and duration of relapses and hospitalisations in the 9 months before the trial and during the 18-month intervention and follow-up period were recorded. ‘Relapse’ was defined as an exacerbation of psychotic symptoms that lasted for > 2 weeks and which resulted in a change in patient management (increased...
observation by the clinical team, increase in antipsychotic medication or both). The start and end dates of each relapse were recorded along with verbatim extractions from the notes detailing changes in symptoms and clinical management. The start and end dates of all hospital admissions for psychiatric purposes were also recorded. Admissions made for preplanned changes in medication were not included.

Information on antipsychotic medication and duration of untreated psychosis (DUP) was also obtained from case notes.

Before accessing participant case notes, research assistants were trained to protocol and extracted hospitalisation and relapse data from six test cases. Inter-rater reliability across assessors was excellent, with 100% agreement on admission (yes/no), number of admissions and number of weeks admitted. Intraclass correlation coefficients for relapse variables were also high, with 0.86 obtained for relapse (yes/no) and 0.97 for number of relapses.

**Results**

**Participants**

A total of 325 patients were identified as being potentially eligible. Of these, 138 declined to be screened for eligibility and 43 did not meet eligibility criteria; 144 consented to take part, of whom 34 withdrew consent before randomisation; 110 completed all baseline assessments and were randomised. Of these, 38 were allocated to brief therapy, 37 to long therapy and 35 to TAU. Data on the primary outcome were collected for 83 (75.5%) participants at 4.5 months, 79 (71.8%) participants at 9 months and 76 (69.1%) participants at 18 months. Full data on relapse and hospitalisation were available for 108 participants (98.2%). Figure 8 shows the participant flow through the trial.

Tables 7 and 8 present baseline demographic, psychiatric and substance use information for participants in each trial arm. Participants were mostly male and aged in their mid-20s. The majority were unemployed. They had a history of psychosis of < 18 months and had been using cannabis for around 10 years, having begun using cannabis in their early teenage years. The majority (n = 100, 90.9%) met criteria for cannabis use dependence. Participants had been using cannabis on 59 out of the 90 previous days on average (SD 27.5 days), consuming an average of 107 g of cannabis in the same time period. The average amount of cannabis per cannabis-using day was 1.7 g (SD 1.5 g). The majority of participants were smoking mostly skunk (78.2%), with 20% smoking mostly resin and the remainder (1.8%) smoking equal amounts of each. More than four out of five participants were contemplating changing their cannabis use at entry to the study according to the RTCQ, with 53.2% identified as being at the ‘contemplation’ stage and 31.2% at the ‘action’ stage.

**Validity of substance use self-reports**

Comparisons of participants’ self-reported cannabis use on the TLFB with hair samples and care co-ordinator reports (abbreviated TLFB and clinician drug use scales) indicated adequate concurrent validity. The agreement between cannabis use identified in hair samples and cannabis use reported by participants was $\kappa = 0.61$. The mean agreement between participant self-reports and care co-ordinator reports averaged across the four assessment time points was $\kappa = 0.49$. It should be acknowledged that the percentage of patients (71%) from whom we were unable to take hair samples is relatively high. This group consists of both those who refused to give hair and those with insufficient head hair to take an adequate sample. The remaining sample may therefore be subject to unknown bias. There were significant ($p < 0.001$) associations between participant self-reports and care co-ordinator reports with regard to total weight (in grams) of cannabis consumed at each time point, with an average intraclass correlation coefficient of 0.61. There were also significant associations between care co-ordinator reports on the Drug Use Scale of the clinician rating scales and weight of cannabis consumed as reported by participants ($p = 0.44$).
Referred to the trial as potentially eligible $(n=325)$

- Excluded $(n=181)$
  - Did not meet inclusion criteria, $n=43$
  - Declined to participate, $n=138$

Consented $(n=144)$

- Withdrawn prior to randomisation $(n=34)$

Randomised $(n=110)$

- Allocated to brief therapy $(n=38)$
  - Did not receive allocated intervention $(n=8)$
    - Withdrawn, $n=1$
    - DNA, $n=7$
  - Allocated to long therapy $(n=37)$
    - Did not receive allocated intervention $(n=7)$
    - Withdrawn, $n=1$
    - DNA, $n=6$
  - Allocated to TAU $(n=35)$
    - Withdraw, $n=5$
    - Deceased, $n=1$

- 31 completed primary outcome at 4.5 months (81.6%)
- 28 completed primary outcome at 4.5 months (75.7%)
- 24 completed primary outcome at 4.5 months (68.6%)

- 29 completed primary outcome at 9 months (76.3%)
- 26 completed primary outcome at 9 months (70.3%)
- 24 completed primary outcome at 9 months (68.6%)

- 26 completed primary outcome at 18 months (68.4%)
- 28 completed primary outcome at 18 months (75.7%)
- 22 completed primary outcome at 18 months (62.9%)

**FIGURE 8** Consolidated Standards of Reporting Trials (CONSORT) flow diagram showing participant flow through the trial. DNA, did not attend.
## Baseline demographic, psychiatric and substance use variables in the three treatment arms

<table>
<thead>
<tr>
<th>Variable</th>
<th>TAU (n = 35)</th>
<th>Brief therapy (n = 38)</th>
<th>Long therapy (n = 37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>23.4 (3.8)</td>
<td>24.9 (5.6)</td>
<td>24.1 (5.4)</td>
</tr>
<tr>
<td>Gender: male, n (%)</td>
<td>30 (85.7)</td>
<td>34 (89.5)</td>
<td>34 (91.9)</td>
</tr>
<tr>
<td>Living arrangements, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone/house-share/hostel</td>
<td>15 (42.9)</td>
<td>14 (36.8)</td>
<td>15 (40.5)</td>
</tr>
<tr>
<td>With partner or family</td>
<td>20 (57.1)</td>
<td>24 (63.2)</td>
<td>22 (59.5)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>33 (94.3)</td>
<td>35 (92.1)</td>
<td>34 (91.9)</td>
</tr>
<tr>
<td>Black and minority ethnic</td>
<td>2 (5.7)</td>
<td>3 (7.9)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>Attended higher education, n (%)</td>
<td>21 (60.0)</td>
<td>16 (42.1)</td>
<td>19 (51.4)</td>
</tr>
<tr>
<td>Employment, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed/retired</td>
<td>27 (77.1)</td>
<td>30 (78.9)</td>
<td>32 (86.5)</td>
</tr>
<tr>
<td>Employed/self-employed</td>
<td>4 (11.4)</td>
<td>2 (5.3)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td>Student</td>
<td>4 (11.4)</td>
<td>6 (15.8)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>History of psychosis (months), median (range)</td>
<td>17.2 (2.3–57.0)</td>
<td>13.4 (1.4–59.6)</td>
<td>17.5 (1.8–62.8)</td>
</tr>
<tr>
<td>DUP, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 4 months</td>
<td>17 (54.8)</td>
<td>13 (37.1)</td>
<td>10 (30.3)</td>
</tr>
<tr>
<td>&gt; 4 months</td>
<td>14 (45.2)</td>
<td>22 (62.9)</td>
<td>23 (69.7)</td>
</tr>
<tr>
<td>Adherent to medication (DAI), n (%)</td>
<td>25 (71.4)</td>
<td>30 (78.9)</td>
<td>30 (81.1)</td>
</tr>
<tr>
<td>Diagnosis (SCID), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>18 (51.4)</td>
<td>20 (52.6)</td>
<td>16 (43.2)</td>
</tr>
<tr>
<td>Schizophreniform disorder</td>
<td>3 (8.6)</td>
<td>3 (7.9)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>Schizoaffective disorder</td>
<td>3 (8.6)</td>
<td>5 (13.2)</td>
<td>5 (13.5)</td>
</tr>
<tr>
<td>Delusional disorder</td>
<td>3 (8.6)</td>
<td>2 (5.3)</td>
<td>4 (10.8)</td>
</tr>
<tr>
<td>Substance-induced psychosis</td>
<td>3 (8.6)</td>
<td>2 (5.3)</td>
<td>1 (2.7)</td>
</tr>
<tr>
<td>Psychotic disorder NOS</td>
<td>5 (14.3)</td>
<td>6 (15.8)</td>
<td>8 (21.6)</td>
</tr>
<tr>
<td>PANSS score, mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>14.9 (3.1)</td>
<td>15.4 (4.5)</td>
<td>14.8 (4.7)</td>
</tr>
<tr>
<td>Negative</td>
<td>14.1 (5.4)</td>
<td>15.1 (3.8)</td>
<td>13.0 (4.9)</td>
</tr>
<tr>
<td>General</td>
<td>32.7 (6.8)</td>
<td>35.6 (7.1)</td>
<td>33.8 (7.2)</td>
</tr>
<tr>
<td>GAF score, mean (SD)</td>
<td>37.9 (9.0)</td>
<td>35.1 (7.2)</td>
<td>39.0 (10.5)</td>
</tr>
<tr>
<td>CDSS score, mean (SD)</td>
<td>5.7 (5.5)</td>
<td>7.7 (4.6)</td>
<td>7.3 (3.9)</td>
</tr>
<tr>
<td>Anxiety (BAI), mean (SD)</td>
<td>14.8 (10.9)</td>
<td>17.1 (11.7)</td>
<td>20.3 (12.8)</td>
</tr>
<tr>
<td>Relapsed (9 months pre baseline), n (%)</td>
<td>18 (51.4)</td>
<td>16 (42.1)</td>
<td>17 (45.9)</td>
</tr>
<tr>
<td>Admitted (9 months pre baseline), n (%)</td>
<td>7 (20.0)</td>
<td>6 (15.8)</td>
<td>10 (27.0)</td>
</tr>
<tr>
<td>History of cannabis use (years), mean (SD)</td>
<td>9.0 (4.3)</td>
<td>10.3 (5.3)</td>
<td>10.4 (5.5)</td>
</tr>
<tr>
<td>Substance use disorder (SCID), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cannabis abuse</td>
<td>2 (5.7)</td>
<td>5 (13.2)</td>
<td>3 (8.1)</td>
</tr>
<tr>
<td>Cannabis dependence</td>
<td>33 (94.3)</td>
<td>33 (86.8)</td>
<td>34 (91.9)</td>
</tr>
<tr>
<td>Alcohol abuse</td>
<td>3 (8.6)</td>
<td>2 (5.3)</td>
<td>2 (5.4)</td>
</tr>
<tr>
<td>Alcohol dependence</td>
<td>1 (2.9)</td>
<td>2 (5.3)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

NOS, not otherwise specified.
Treatment delivered and treatment fidelity

Brief therapy was better attended than long therapy, with 57.9% of those allocated to brief therapy attending at least 75% of the sessions offered compared with just 29.7% of those allocated to long therapy attending at least 75% of the sessions offered. The median number of therapy sessions delivered to participants was 9.75 for brief therapy and 11.0 for long therapy. Fifteen participants (20%) attended two or fewer therapy sessions, seven allocated to long therapy and eight allocated to brief therapy.

The number of items rated as compliant on the treatment fidelity scales ranged from 14 out of 16 (87.5%) to 16 out of 16 (100%) across the 20 digitally recorded sessions rated.

Table 8: Frequency and amount of substance use at baseline (previous 90 days)

<table>
<thead>
<tr>
<th>Variable</th>
<th>TAU (n = 35)</th>
<th>Brief therapy (n = 38)</th>
<th>Long therapy (n = 37)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (min.–max.)</td>
<td>Median (min.–max.)</td>
<td>Median (min.–max.)</td>
<td>χ², p-value</td>
</tr>
<tr>
<td>Proportion of days abstinent from cannabis (%)</td>
<td>42.2 (0–88.9)</td>
<td>21.1 (0–92.2)</td>
<td>26.7 (0–6.7)</td>
<td>1.4, 0.50</td>
</tr>
<tr>
<td>Total cannabis use (g)</td>
<td>87.8 (7.5–322.5)</td>
<td>108.3 (1.2–640.0)</td>
<td>42.8 (1.0–377.4)</td>
<td>4.4, 0.11</td>
</tr>
<tr>
<td>Average amount of cannabis used per cannabis-using day (g)</td>
<td>1.3 (0.3–9.4)</td>
<td>1.5 (0.1–7.1)</td>
<td>1.2 (0.1–4.2)</td>
<td>5.3, 0.069</td>
</tr>
<tr>
<td>Proportion of days abstinent from all substances (%)</td>
<td>31.1 (0–84.4)</td>
<td>13.9 (0–82.2)</td>
<td>22.2 (0–81.1)</td>
<td>1.4, 0.49</td>
</tr>
</tbody>
</table>

Max., maximum; min., minimum.

Discussion

We have conducted the largest trial to date of integrated MiCBT in a first-episode cannabis-using population. Our aim was to evaluate the effectiveness of MiCBT and compare the efficacy of a brief intervention (4.5 months) with that of a longer one (9 months), hypothesising that the MiCBT intervention would be efficacious in reducing substance use in people with early psychosis and that the brief version would be as efficacious as the longer version.

The outcomes of the trial are not yet available and we have therefore outlined the trial, described the sample at baseline and reported recruitment and retention rates. Indications are that despite the challenges associated with conducting trials with this client group the study has been successful in recruiting and retaining participants over a long follow-up period. We worked closely with the early-intervention teams to set up the study and identify potentially eligible participants and employed assertive engagement strategies once participants were recruited, seeing them in their own homes, arranging appointments flexibly but with persistence and conducting repeat visits for missed therapy and research appointments when necessary.

The refusal rate for participants identified as potentially eligible to take part was higher than those in recently conducted RCTs that had shorter intervention and follow-up periods, but was in line with rates obtained from previously conducted studies. We note that this was a non-treatment-seeking sample and all service users identified by their case managers as cannabis users were considered for inclusion. We do not have information on the service users who refused to participate or to be screened for eligibility and therefore cannot compare them with those included in the study. This may reduce the generalisability of our findings. It may be that those who declined the invitation to participate were more likely to be at a pre-contemplation stage of change. We found that > 80% of those randomised were contemplating changing their cannabis use at baseline. It is logical to assume that those who were contemplating change were more likely to agree to take part than those who were not.
Our assertive engagement strategies resulted in good retention for follow-up assessment. Almost 70% of the sample was retained at 18 months’ follow-up. Many of those who were lost to follow-up had moved away without leaving a forwarding address and were, therefore, not contactable. Take up of therapy was satisfactory, with 80% attending at least two sessions. Brief therapy was better attended than long therapy with twice the number of brief therapy participants attending 75% of the sessions offered. The median number of therapy sessions attended was similar in the two therapy arms, indicating that a brief form of the intervention may be more acceptable than a longer form. Qualitative interviews with therapy participants will seek to establish why brief therapy was better received and why some people refused therapy when offered it.

The sample is comparable with those in the four earlier RCTs of interventions with young cannabis-using recent-onset psychosis patients, three of which had not reported their results at the time that the ReCAP trial commenced, and to early-intervention service users generally: the majority were male, in their 20s and unemployed and had been using cannabis since their mid-teens. We recruited from services in various geographical locations encompassing both urban and rural populations and we are, therefore, confident that the sample is representative of our target population and that the results will be generalisable. We note that frequency of cannabis use, measured by percentage days abstinent, was higher in this trial than the previously reported trials with regard to percentage days abstinent. The amount of cannabis consumed is difficult to compare between the trials because of methodological differences, but ReCAP participants appeared to be smoking approximately 50% more cannabis than CapOpus participants. Rates of abuse/dependence on other substances were much lower in the ReCAP trial than in the CapOpus trial (< 10% vs. approximately 50%), which may indicate that our sample was to some extent a ‘purer’ sample of cannabis users and more in line with the study by Bonsack and colleagues, which excluded those who were dependent on other substances and purposely recruited ‘heavier’ cannabis users. Rates of abuse and dependence on other substances were not reported in the other two trials and comparisons cannot be made.

The three previously conducted trials of integrated MiCBT in early psychosis found that the intervention did not confer an advantage over the control conditions in terms of reducing cannabis use or improving clinical outcomes. The results of the ReCAP trial will, therefore, be an important addition to the evidence base; with the longest intervention of all of the trials and the longest follow up, the results will be crucial in determining whether MiCBT can reduce cannabis use or a new therapeutic approach to cannabis use in psychosis will be required. It is perhaps noteworthy in this context that none of the recent trials, including the ReCAP trial, has involved families, possibly because of the constraints on recruitment of selecting only those who have regular contact with relatives. However, two studies that have found benefits from psychological therapy for people with psychosis and substance use have included a family-based component.

The strengths of this study include the high-quality randomisation process, the single-blind design, the range of substance use, symptom and functional outcomes and the 18-month follow-up period. The majority of participants engaged with the intervention and we were able to follow up a high proportion of participants. However, a significant minority (one in five) did not engage well with the intervention despite our assertive approach and future research should seek to understand influences on engagement in therapy as well as treatment preferences overall. Limitations include the potential bias resulting from early-intervention service users under-reporting substance use to their case managers and therefore not being considered eligible for referral; likewise, some potential participants may not have perceived their cannabis use to be problematic and declined to take part. Nonetheless, as the largest RCT conducted to date of an intervention to reduce cannabis use in first-episode psychosis and the only trial to compare brief therapy with longer therapy, we expect the results of this trial to be of considerable interest to academics and clinicians concerned with the development of an evidence base for the treatment of this client group.
Chapter 4 Discussion

We developed and evaluated three interventions aimed at reducing relapse/deterioration in physical health in young people with recent-onset psychosis. The first of these, CR, was hypothesised to enhance the efficacy of CBT, with symptoms predicted to reduce faster and further during CBT preceded by CR. A secondary hypothesis was that CR would enhance the efficiency of CBT, facilitating shorter courses or greater progress. Our hypotheses were partially supported. CR was not associated with significantly lower PSYRATS scores over the period of study. The effect of CR on PANSS score was also non-significant, although insight changed significantly more positively after CR than after SC. However, the hypothesis that CR would improve the efficiency of CBT was supported. After CR, participants made the same amount of progress in half the number of CBT sessions. There was no significant effect of CR on SOFAS score, depression, self-esteem, time to relapse or readmission. Our findings suggest that CR delivered by relatively unskilled workers can improve the efficiency of subsequent CBT, enabling participants and therapists to achieve the same amount of progress in therapy in approximately half the number of sessions. A substantial increase in the efficiency of CBT implies that the same number of CBT therapists could treat many more patients. Our main recommendation for future research is that a definitive trial of CR-aided CBT should be conducted, with improvement in the efficiency of CBT as the primary outcome measure.

The healthy-living stream aimed to develop an evidence-based acceptable, feasible and effective intervention to encourage activity, improve diet and control weight gain in people recovering from a first episode of psychosis and to evaluate the clinical effectiveness and cost-effectiveness of the newly developed intervention in an exploratory RCT. We succeeded in these aims; early qualitative work confirmed that managing weight gain and staying physically active to prevent weight gain were important issues to service users and the intervention was carefully designed in collaboration with service users to be sensitive to their needs. Participants in the trial engaged well with the intervention and found it to be acceptable. This was reflected in excellent retention throughout the trial, with fewer than 10% of participants lost to follow-up. The healthy-living intervention was associated with a small reduction in BMI compared with the TAU group but the effect size was small (0.11) and the difference was not statistically significant. It could be that a more intensive intervention or more structured exercise programmes are required to achieve a larger effect. The small effect may also have resulted from our focus on weight loss in participants who were already obese rather than prevention of weight gain; this may have been a particularly difficult group to treat. There was evidence to suggest that the intervention may be more effective in participants taking olanzapine and clozapine. It could be that people may be more motivated to lose weight after having experienced medication-associated weight gain or it may be that the effects of dietary change and an increase in activity are larger in this group. Further research is needed to distinguish between the two possibilities. We did not consider measures of cardiovascular vulnerability such as high-density lipoprotein/low-density lipoprotein cholesterol ratio and levels of triglycerides as outcomes that our intervention may have had an impact on. Future research should consider these as outcomes in addition to BMI.

Health- and social-care costs were lower in the TAU group but the difference was not statistically significant and given the limited clinical effectiveness of the intervention it is not clear that the difference would be sufficient to offset the additional costs of providing the intervention. However, full cost data were not available for all participants who completed follow-up and further analysis is planned.

Our main recommendation for research is that further work should be carried out to improve the effectiveness of the healthy-living intervention, particularly focusing on those who are taking olanzapine and clozapine.
The substance use stream optimised an existing intervention aimed at reducing substance use, changing the focus to cannabis use and making it phase specific to the early-intervention period. The ReCAP trial was a well-designed, well-conducted trial that was successful in recruiting, engaging and retaining a representative sample of young cannabis users. In total, 80% engaged with therapy and almost 70% were retained until the 18-month follow-up. Outcome data are not yet available but will be of significant interest to academics and clinicians in the field.

Considering the trials overall, we anticipated that if a phase-specific intervention was effective we would see a trend in that trial towards reduced relapse rates. This was not the case. We also anticipated that there might be a trend towards lower relapse rates in the intervention groups across all three trials. This was also not the case. There was little evidence overall that any of the interventions had an impact on relapse, even at a trend level (Table 9).

**Future work**

A common theme from all three trials was the interest in research shown by service users and staff in early-intervention services. This was manifest from the beginning in the eagerness of service users to participate in the qualitative research leading to the development of the interventions. It was also apparent in the openness of early-intervention services to our research teams and the willingness of early-intervention service staff and managers to publicise and support the research. We conclude that early-intervention services are particularly conducive to ongoing research programmes and would recommend that consideration be given to funding an ongoing programme of phase-specific research in early-intervention services.

**TABLE 9** Number of participants who relapsed across the three trials

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Intervention group, n (%)</th>
<th>Control group, n (%)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>8 (26.7)</td>
<td>11 (35.5)</td>
<td>$\chi^2(1) = 0.55, p = 0.457$</td>
</tr>
<tr>
<td>Healthy living</td>
<td>15 (30.6)</td>
<td>12 (27.9)</td>
<td>$\chi^2(1) = 0.08, p = 0.776$</td>
</tr>
<tr>
<td>MiCBT</td>
<td>24 (32.4)</td>
<td>13 (37.1)</td>
<td>$\chi^2(1) = 0.24, p = 0.628$</td>
</tr>
</tbody>
</table>
Acknowledgements

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Christine Day (Research Assistant) contributed to devising the assessments for the CR trial, recruited and assessed participants and prepared the data for analysis and contributed to the writing of this report.

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Rebecca Pedley (Research Assistant) contributed to the day-to-day management of the InterACT trial, implemented the recruitment strategy and led on the acceptability qualitative interviews and contributed to the writing of this report.

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Appendix 1 The InterACT trial service user interview topic guide

The HELPER trial: the healthy living intervention

First qualitative interview schedule prompt sheet

1. Can you tell me when your mental health problems first started?
   Probe
   • What do you remember about the onset of your problems?
   • What symptoms were you experiencing?
   • What did you think was happening to you at the time?
   • How did you react initially to experiencing symptoms?
   • What do you think caused the problems that you have experienced?
   • How is life different now to before your mental health problems started?

2. What sort of things have you noticed make your mental health problems either better or worse?
   Probe
   • Do you think that there is anything that you or anyone else can do to help control your symptoms?
   • Can you identify any particular situations/triggers that make your symptoms worse?
   • How do you cope with these situations?

3. What if any medication are you taking at the moment?
   Probe
   • Can you tell me the name and dosage of your medication?
   • How long have you been taking this medication?
   • Do you manage to take your medication exactly as it is prescribed?
   • How do you make sure that you remember to take it?
   • Do you feel that taking the medication helps you in any way?
   • Is there anything that you don't like about taking medication?

4. If not taking medication
   Probe
   • Why do you not take medication? Is it because you have never been asked to or is it a decision on your part?
   • How would you feel about taking medication to help your mental health problems if your doctor asked you to?

5. What information have you been given regarding medication?
   Probe
   • What information have they been given?
   • Who gave them this information/how did they obtain it?
   • Do they know about any potential side effects?
   • Do they experience any unpleasant side effects, how much do these bother them and how do they cope with them?
6. What sort of things do you think are important for maintaining a healthy lifestyle?
    
    * Probe

    - What do you do at the moment to stay fit and healthy?
    - Have there been any changes to your lifestyle since you first experienced mental health problems?

7. Has your lifestyle changed in any way since you first developed mental health problems?

    - Tell me a bit about the types of things you like to eat
      
      - Do you eat regular meals at set times or are you more likely to graze on snacks between meals?
      - Can you tell me how many portions of fruit or vegetables you eat in a typical day?
      - How often do you eat fried food?
      - What type of bread do you prefer?
      - How much coke or how many other soft drinks do you have in an average day?

    - Do you smoke cigarettes?
      
      - If yes, how many in a typical day?
      - How long have you smoked for?

    - Do you drink alcohol?
      
      - If yes, how much do you drink on an average day?

    - Do you take any drugs that haven’t been prescribed by a doctor, such as cannabis?
      
      - If yes, what do you take and how much in a typical day/week?

8. Do you consider that you have any problems with your weight?
    
    * Probe

    - What do you consider these problems to be?
    - Have they ever tried to lose/gain weight?
    - How did they do this and how successful was it?

9. Would you like to make any changes to your current lifestyle in order to make it healthier?
    
    * Probe

    - What changes if any would you like to make?

10. What help or advice (if any) would you like to have in order for you to make healthy changes to your lifestyle?
    
    * Probe

    - Who do you think is the best person to give this advice, e.g. CPN, GP, practice nurse?
    - Where would they like to receive advice, e.g. hospital, GP surgery?
11. What type of healthy living intervention would you like to receive?

- If free access to a gym or other fitness facility was made available do you think that you would use it?
- Would you prefer to go with a group of people or alone?
- Where do you think the best place to deliver the intervention would be (probe – mental health setting, community setting, other)?
- What time of day would you prefer to attend a healthy living group (probe – afternoon, morning, early evening; fixed time, flexible times; how long, frequency of sessions; rationale for choice)?
- What you think would be the best way to run the intervention (probe – explicitly here, i.e. games, live demonstrations, e.g. healthy eating, workbooks, small group work, discussion, bringing in some experts, e.g. dieticians, hands on, e.g. practical such as an actual cooking class; open or closed group)?
- Who do you think are the best people to deliver the intervention (probe – MHW, users, experts in health promotion, etc.)?
- What do you think are the things that will make the intervention successful in helping people to develop a healthier lifestyle (probe – free access to exercise facilities, etc.) and what things might get in the way of it being successful [probe – reasons and solutions, i.e. what do you think might help us overcome these (barriers) or how can we make sure we do this (facilitators)]?

12. Is there anything else that you would like to tell me about the service you are receiving? Or anything about the type of healthy living intervention that you would like to receive?

Thank you for giving up your time to see me today. It has been very helpful talking to you.
Appendix 2  The InterACT trial health professional interview topic guide

The HELPER trial: the healthy living intervention

Interview/focus group schedule for early intervention services/primary care staff

1. Introduction and presentation/information sheet on synthesis of our findings from phase 1 (i.e. content elements).
2. What are your views of your roles and responsibilities in the physical health care of people with psychosis (probe – reasons, i.e. policy, professional, etc.)?
3. What training have you received in providing health education advice to service users about healthy living (probe – adequacy of training; mandatory or voluntary)?
4. What training have you received in assessing and managing physical health problems (probe – adequacy of training; mandatory or voluntary)? Do you routinely assess for unwanted effects of medication (probe – how do they do this, what side effects do they assess for)?
5. Would you be prepared to run healthy living groups within the early intervention service (probe – exactly who, resource implications, training, etc.)?
6. If healthy living groups were to be delivered by the early intervention service, what would help them to run smoothly (probe – venue, group leader, time of day)?
7. Do you think there might be any obstacles to the healthy living groups running smoothly in the early intervention service (probe – pressure of work, service user apathy, not a priority, etc.)?
Appendix 3  The InterACT trial healthy living intervention booklet
Max Marshall, Karina Lovell, Alison Wearden, Jeff Warburton, Nusrat Husain, Tim Bradshaw & Diane Escott.
CONTENTS

1. What is the purpose of this booklet?

2. How do I use this booklet?

3. Why is healthy living important for me?

4. Information about Healthy Living.

Calculating BMI

Diet

Introduction.

Why do I need a healthy balanced diet?

What is a healthy balanced diet?

How can I eat more healthily?

How can I shop more healthily?

How can I cook more healthily?

Physical activity

Why is physical activity important?

What is the recommended amount of physical activity that we should take?

How much physical activity do you currently take?

Becoming more physically active?
Local resources to help you become more active!

5. Getting started – making goals and action plans
   **GOALS**
   **ACTION PLANS**

6. Getting going – putting your plan into action

7. Keeping going

8. The Healthy Living Groups
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1) why eat more.pdf
http://www.dh.gov.uk/en/Publichealth/Healthimprovement/FiveADay/DH_4069867

2) healthy eating made easy.pdf

3) fuel for living.pdf
http://www.5aday.nhs.uk/DownloadsResources/documents/Fuel_for_Living_Rec
ipe_Booklet.pdf

4) http://www.eatwell.gov.uk/healthydiet/eighttipssection/8tips/

5) The eatwell plate and accompanying explanatory plate tips.
1. What is the purpose of this booklet?

Thank you for agreeing to take part in this healthy living study. Together, with your help, our aim is to develop ways of helping people to improve their health by making healthy changes to their lifestyle.

This booklet is designed to give you lots of advice and tips on healthy eating and physical activity. It has information about local resources you may want to use, as well as information on some healthy living groups. It gives practical tips on eating healthily on a budget and has some great recipes which you and your family may want to try.

The booklet has been designed to fit in with your sessions with your Support Time Recovery (STR) worker. This is when you will work together looking at changes you might want to make to your diet and activity levels. This may include setting yourself goals and making action plans of how to achieve your goals. We hope you find this journey towards a healthier lifestyle fun, interesting and enjoyable.
2. How do I use this booklet?

This book is for you. It includes the following sections

- Why is healthy living important for me?
- Information about Healthy Living.
  - Diet
  - Physical activity
- Getting started – making goals and action plans
- Getting going – putting your plan into action
- Keeping going
- The Healthy Living Group

Please take copies for your friends or members of your family if you think this may be helpful to you. It is available in a written form or audio or CD. Copies of the booklet are also printed in Urdu. Please ask your STR worker if you or a member of your family would like a copy.

Do I have enough information? This booklet is yours. It is for you to keep and dip in and out of whenever you need to. The main purpose is to help you to find out more about healthy diets, physical activity and the changes you want to make to your lifestyle. This section in the booklet tells you about what a healthy diet is and how
much physical activity you should try to take each week. This information is based on guidelines given by doctors and experts who work for the government. These two sections are for you to use as a resource, they list the local resources, telling you where local leisure centres are, gyms and different types of activities. We have also tried to list lots of great recipes that you can try and space for you to add your own.

**How do I get started?** Most of us know that it is good for us to eat a healthy diet and stay physically active but for many of us, it’s just getting started. This booklet will help you to do just that. Together with your STR worker you can make changes in your daily life that allow you to eat a more healthy diet and keep up a daily level of activity that is right for you. Your STR worker will help you to make a plan for any changes you would like to make in your life about the types of food you eat and the kind of activities you would like to take part in.

**Getting going:** Once you have made a plan, your STR worker will help you put your plan into action. The booklet provides advice on getting going with your plan, and will help you to keep a record of your plan.

**Keeping going:** If you have ever made changes before you will know that it is the keeping going that is hard. Don’t worry! The next section will help you, with lots of tips and advice on how to keep going with any changes until they become part of your everyday life.
**The Healthy Living Group:** The final section tells you about the healthy living groups. These are a series of groups run by the Support Time Recovery workers, and are aimed at helping you to make changes to your lifestyle and keep going with your healthy living plan. The groups can give you lots of tips, advice and ideas. They also give you the chance to meet others who are trying to make changes to their diet and/or activity levels. The purpose of the group is to be fun and enjoyable and to give extra support. You are free to join in as many of the group sessions as you want to.

We really hope you enjoy making changes to your lifestyle and enjoy using this booklet along with all the help from your STR worker.

**3. Why is healthy living important for me?**

Healthy living is not just something our doctors like to talk about. It is important for everyone. Having a good diet and remaining physically active is good for our bodies and can help us to feel better about ourselves too.

By eating well and exercising we can maintain a healthy weight, which then helps us to keep a healthy heart and body. This in turn, helps us to live longer, healthier and happier lives. It also helps us to avoid chest complaints, weight problems, heart disease, diabetes and cancer.
Healthy Living

Current advice tells us that healthy living includes:

- Eating a balanced diet
- Taking regular exercise
- Keeping weight within recommended limits

You may have some of your own to add....
4. Information about Healthy Living.

Calculating BMI

The following information is taken from the Food Standards Agency Website, “Eat Well, Be Well”

One way to get an idea of your ideal weight is to calculate your own Body Mass Index (BMI) using the helpful link below to the food standards agency website. This can help to give you an idea of what is a healthy weight for your height.

http://www.eatwell.gov.uk/healthydiet/healthyweight/bmicalculator/

BMI is based on your height and weight measurements. You will need to either take your height in metres and centimetres and your weight in kg or take your height in feet and inches and your weight in stones and pounds.

Or, as noted on the website, you can use the height/weight chart to get an idea of your ideal weight range for your height.

Another way of finding out if you are overweight is to check your waist size against your height.

http://www.eatwell.gov.uk/healthydiet/healthyweight/yourbodyshape/

We know that carrying too much weight around our middle is associated with health problems such as heart disease and diabetes.
Have a go at calculating your BMI or check your weight against height or waist measurement. Your STR worker can help you with this.

If you would now like to lose some weight here are the main things to remember:

- Only eat as much as you need to. Don’t eat if you are not hungry.
- Eat more of the foods that are healthy, low fat, low-sugar, fresh fruit and veg and wholegrains
- Try to be more active everyday
Diet

Introduction: What are the guidelines?

The following pages give a summary of the advice provided by the department of health and the food standards agency about healthy diets. You’ve probably heard of the five a day campaign. This tells us that we should all aim to eat at least five portions of fruit and vegetables a day. All of the information listed can be obtained online. We have included the web page references. Just type this into your web browser to find out more.

Five a day: On the next page is a leaflet which tells you why it is good for you to eat more fruit and veg. There is a quick quiz to find out if you are eating enough fruit and veg. A colourful poster tells you the size of one portion. Reproduced under the terms of the Click-Use Licence.

What else is in this section?

Following this we have tried to list lots more information on:

- Why do I need a healthy balanced diet?
- What is a healthy balanced diet?
  - Starchy foods: rice, whole-wheat pasta, bread, & potatoes
  - Fruit and vegetables
  - Meat, fish, eggs and beans
  - Milk and dairy foods
  - Foods containing fat and sugar (in moderation)
- How can I eat more healthily?
  Tips on eating more healthily from the major food groups.
How can I shop more healthily?
Top tips on how to shop for healthy foods on a budget.

How can I cook more healthily?
Recipe ideas to try and space to add your own.

Why eat more?
Eating more fruit and vegetables may help reduce the risk of the two main killers in this country – heart disease and some cancers.

Aim to eat at least 5 portions of a variety of fruit and vegetables a day. Fresh, frozen, chilled, canned, 100% juice and dried fruit and vegetables all count.

A portion is equivalent to 80 grams (about 3 ounces). You can see some examples of portion sizes on the front and back of this card.

The fruit and vegetables contained in convenience foods – such as ready meals, pasta sauces, soups, and puddings – can contribute to 5 A DAY. But convenience foods can also be high in added salt, sugar or fat – which should only be eaten in moderation – so it’s important always to check the nutrition information on food labels.

Are you eating at least 5 A DAY?

1. How many portions of fruit - of any kind - do you eat on a typical day?
   Juice can only count as 1 portion a day, however much you drink.
   Portions of fruit per day: ________________

2. How many portions of vegetables do you eat on a typical day?
   Potatoes are a starchy food so they don’t count towards 5 A DAY.
   Portions of vegetables per day: ________________

Scoring
Add up the numbers you gave in your answers to questions 1 and 2:

If the total is 5 or more – Well done. You are probably meeting the 5 A DAY target. If the total is less than 5 – Try some of the ideas in the 5 A DAY booklet to increase the amount of fruit and vegetables you eat.

For more information and a copy of the booklet: www.dh.gov.uk/fiveaday

This section is based on work carried out by Professor Harris and Professor Higgs as part of their research.
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WHAT DO I NEED TO KNOW?

WHY EAT 5 A DAY?
INTRODUCTION BY DR CHRIS STEELE

Eating more fruit and vegetables is one of the best ways to reduce the risk of cancer and protect against heart disease. Fruit and vegetables are also generally low in calories and fat, making them ideal for anyone watching their weight. What's more, eating a variety of at least 5 portions of fruit and veg a day is a positive way to be healthier, as it concentrates on what you can eat rather than what you should cut out from your diet.

There are so many different types of fruit and vegetables that there's something for everyone. To get the maximum benefits, it is important to eat a variety of fruit and vegetables. Evidence suggests that the easiest way of achieving 5 A DAY is to eat more fruit and veg, more often.

Turn to the back page of the booklet to find out what counts as a portion.

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Why do I need a healthy balanced diet?

Eating a healthy balanced diet can significantly reduce your chances of:

- Having a stroke
- Developing diabetes
- Heart disease
- Bowel cancer
- Parkinson’s disease

What is a healthy balanced diet?

Balancing your diet will get easier the more you do it. To help you to see the balance between the five food groups, the Food Standards Agency has produced the Eatwell plate.

Try to divide each day’s food in the proportions that you see on the plate and you’ll be well on the way to a healthy diet.
How can I eat more healthily?

The food standards agency website lists lots of practical tips for making healthy food choices.

http://www.eatwell.gov.uk/healthydiet/eighttipssection/8tips/

The information listed tells you that it is important to try to eat the right amount of food for your activity levels and to have a range of foods in your diet.

Only eat as much as you need to. Don’t eat if you are not hungry.
Eat more of the foods that are healthy, low fat, low-sugar, fresh fruit and veg and wholegrains

Try to be more active everyday

Here are some of the 8 tips they provide

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http://www.eatwell.gov.uk/healthydiet/eighttipssection/8tips/

These practical tips can help you make healthier choices. The two keys to a healthy diet are eating the right amount of food for how active you are and eating a range of foods to make sure you're getting a balanced diet.

A healthy balanced diet contains a variety of types of food, including lots of fruit, vegetables and starchy foods such as wholemeal bread and wholegrain cereals; some protein-rich foods such as meat, fish, eggs and lentils; and some milk and dairy foods.

Base your meals on starchy foods
Eat lots of fruit and veg
Eat more fish
Cut down on saturated fat and sugar
Don’t skip breakfast

Base your meals on starchy foods
Starchy foods such as bread, cereals, rice, pasta and potatoes are a really important part of a healthy diet. Try to choose wholegrain varieties of starchy foods whenever you can.

Starchy foods should make up about a third of the food we eat. They are a good source of energy and the main source of a range of nutrients in our diet. As well as starch, these foods contain fibre, calcium, iron and B vitamins.
Most of us should eat more starchy foods - try to include at least one starchy food with each of your main meals. So you could start the day with a wholegrain breakfast cereal, have a sandwich for lunch, and potatoes, pasta or rice with your evening meal.

Some people think starchy foods are fattening, but gram for gram they contain less than half the calories of fat. You just need to watch the fats you add when cooking and serving these foods, because this is what increases the calorie content.

**Why choose wholegrain foods?**

Wholegrain foods contain more fibre and other nutrients than white or refined starchy foods.

We also digest wholegrain foods more slowly so they can help make us feel full for longer.

Wholegrain foods include:
- Wholemeal and wholegrain bread, pitta and chapatti
- Wholewheat pasta and brown rice
- Wholegrain breakfast cereals

**Eat lots of fruit and veg**

Most people know we should be eating more fruit and veg. But most of us still aren’t eating enough.

Try to eat at least 5 portions of a variety of fruit and veg every day. It might be easier than you think.

You could try adding up your portions during the day.

For example, you could have:
- a glass of juice and a sliced banana with your cereal at breakfast
- a side salad at lunch
- a pear as an afternoon snack
- a portion of peas or other vegetables with your evening meal

You can choose from fresh, frozen, tinned, dried or juiced, but remember potatoes count as a starchy food, not as portions of fruit and veg.
**Eat more fish**

Most of us should be eating more fish - including a portion of oily fish each week. It’s an excellent source of protein and contains many vitamins and minerals.

Aim for at least two portions of fish a week, including a portion of oily fish. You can choose from fresh, frozen or canned - but remember that canned and smoked fish can be high in salt.

**What are oily fish?**
Some fish are called oily fish because they are rich in certain types of fats, called omega 3 fatty acids, which can help keep our hearts healthy.

**How much oily fish?**
Although most of us should be eating more oily fish, women who might have a baby one day should have a maximum of 2 portions of oily fish a week (a portion is about 140g). And 4 is the recommended maximum number of portions for other adults.

**Examples of oily fish**
Salmon, mackerel, trout, herring, fresh tuna, sardines, pilchards, eel

**Examples of white or non-oily fish**
Cod, haddock, plaice, coley, tinned tuna, skate, hake

Shark, swordfish and marlin
Don’t have more than one portion a week of these types of fish. This is because of the high levels of mercury in these fish.

Anyone who regularly eats a lot of fish should try and choose as wide a variety as possible.

**Cut down on saturated fat and sugar**

**Fats**
To stay healthy we need some fat in our diets. What is important is the kind of fat we are eating. There are two main types of fat:

- **saturated fat** - having too much can increase the amount of cholesterol in the blood, which increases the chance of developing heart disease
- **unsaturated fat** - having unsaturated fat instead of saturated fat lowers blood cholesterol

Try to cut down on food that is high in saturated fat and have foods that are rich in unsaturated fat instead, such as vegetable oils (including sunflower, rapeseed and olive oil), oily fish, avocados, nuts and seeds.

### Foods high in saturated fat

Try to eat these sorts of foods less often or in small amounts:

- meat pies, sausages, meat with visible white fat
- hard cheese
- butter and lard
- pastry
- cakes and biscuits
- cream, soured cream and crème fraîche
- coconut oil, coconut cream or palm oil

For a healthy choice, use just a small amount of vegetable oil or a reduced-fat spread instead of butter, lard or ghee. And when you are having meat, try to choose lean cuts and cut off any visible fat.

### How do I know if a food is high in fat?

Look at the label to see how much fat a food contains. Generally the label will say how many grams (g) of fat there are in 100g of the food.

Some foods also give a figure for saturated fat, or 'saturates'.

Use the following as a guide to work out if a food is high or low in fat.

### Total fat - what's high and what's low?

- **High** is more than 20g fat per 100g
- **Low** is 3g fat or less per 100g

If the amount of fat per 100g is in between these figures, then that is a medium level of fat.
Saturated fat - what's high and what's low?

**High** is more than 5g saturates per 100g  
**Low** is 1.5g saturates or less per 100g

If the amount of saturates per 100g is in between these figures, then that is a medium level of saturated fat.

Remember that the amount you eat of a particular food affects how much fat you will get from it.

Try to choose more foods that are low in fat and cut down on foods that are high in fat.

Sugar

Most people in the UK are eating too much sugar. We should all be trying to eat fewer foods containing added sugar, such as sweets, cakes and biscuits, and drinking fewer sugary soft and fizzy drinks.

Having sugary foods and drinks too often can cause tooth decay, especially if you have them between meals. Many foods that contain added sugar can also be high in calories so cutting down could help you control your weight.

How do I know if a food is high in added sugar?

Take a look at the label. The ingredients list always starts with the biggest ingredient first.

But watch out for other words used to describe added sugars, such as sucrose, glucose, fructose, maltose, hydrolysed starch and invert sugar, corn syrup and honey. If you see one of these near the top of the list, you know the food is likely to be high in added sugars.

Another way to get an idea of how much sugar is in a food is to have a look for the 'Carbohydrates (of which sugars)' figure on the label. But this figure can’t tell you how much is from added sugars, which is the type we should try to cut down on.

**High** is more than 15g sugars per 100g  
**Low** is 5g sugars or less per 100g

If the amount of sugars per 100g is in between these figures, then that is a medium level of sugars.

Remember that the amount you eat of a particular food affects how much sugars you will get from it.
Sometimes you will only see a figure for total 'Carbohydrates', not for 'Carbohydrates (of which sugars)', which means the figure also includes the carbohydrate from starchy foods.

**Don't skip breakfast**

Breakfast can help give us the energy we need to face the day, as well as some of the vitamins and minerals we need for good health.

Some people skip breakfast because they think it will help them lose weight. But missing meals doesn't help us lose weight and it isn't good for us, because we can miss out on essential nutrients.

There is some evidence to suggest that eating breakfast can actually help people control their weight.

So why not go for a bowl of wholegrain cereal with some low-fat milk and sliced banana and a glass of fruit juice for a healthy start to the day?

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How can I shop more healthily?

What you eat is so important to your health. What you eat today matters because it then becomes what you are tomorrow. You may not think that eating a high fat, low fibre diet, with lots of salt is doing you any harm now. But it’s later on in life that it matters. You can change now what you eat and feel the benefits straight away. But most important, you are making sure that you are not placing yourself at a high risk of developing heart disease and cancer later on.

Making a healthy eating plan starts with you writing down what you are going to cook, writing a shopping list, going shopping and doing the cooking. It seems a lot to do on a budget. But over time it will become easier and save you money in the long run.

Plan your shopping.

To change the way we eat starts with what we buy. This includes what we buy to eat at home or when we are out and about. We need to plan ahead what we are going to eat and therefore what we need to buy.

Knowing in advance what you are going to eat will help you to save money as well. A carefully planned menu will mean that only the things you need to buy will be on your shopping list. If you try to keep to your shopping list you won’t be as tempted to buy lots of extras. If you know how much money you have each week then you can budget your food bill within this. As you go shopping you will start to know how much different foods cost and what you can afford to buy within your budget. It’s all down to the planning.

You can go shopping as many times a week as you like. Some people may like to plan daily what to eat and shop that day, others may prefer to do this every 3 to
4 days or weekly. It’s up to you. No matter how many days you are planning for follow these simple steps.

1) Write yourself a menu

2) Write yourself a shopping list

Remember to have a balanced diet you need to include foods from all the food groups.

- Fruit & Vegetables – fresh is best, but frozen is also good and tinned is fine. Make your basket look like a rainbow! Go for a range of colours.

- Herbs & Spices – make up your own cooking sauces. Find recipes that tell you how to do this as many shop-bought or ready made cooking sauces have lots of added salt and sugar.

- Milk and Cheese – cheese is rich in fat, but is also a good source of protein, vitamins and minerals. Milk is a great food source.

- Eggs – are a great source of food, definitely one for the shopping basket. You can use them in so many different dishes.

- Fish – buy fresh or frozen.

- Meat – visit your local butcher or farmers market. You can buy as much or as little as you like. Meat sold in supermarkets is good but unless they have a butchers stall you will need to buy the quantity sold in the packets.
Grains – remember to include recipes for rice, pasta, peas, beans, lentils, seeds, nuts. Buying whole packets can seem expensive to begin with but a packet of dried pasta may last you a couple of weeks.

3) Go shopping

Remember to consider all the different places you can visit. It’s not just the supermarket that has all the good stuff. To eat healthily means we need to buy lots of fresh food. This usually has a much shorter shelf life than packaged food. Get to know when your local market days are. Get to know where your local green grocers or butchers are. It may surprise you that they are nearer than you think. Walking to the shops is a really good way to keep fit as well.

We also need a good store of basics. To cook healthy meals we need to stock up on rice, pasta, healthy cooking oils, such as olive oil or sunflower oil. Get some good herbs and spices. Packets are fine. Or if you’re green fingered grow your own herbs. Get a supply of pulses, such as lentils, pearl barley. Some supermarkets sell packets of pulses to add to casseroles. You don’t need to buy this all in one go, build a stock up over a couple of months as you try new recipes. Get yourself some good breakfast cereals, go for the less sugary varieties. Look out for ones with wholegrain written on them.

4) Get Cooking

The next section gives lots of advice and tips on healthy cooking Reproduced under the terms of the Click-Use Licence.

Healthy eating does involve doing cooking. But if you think of the benefits to you and your family’s health, it really is worth it. But like with most things, the more you do the easier it gets. You can get others involved too. Involve your family or friends in the kitchen helping out with preparing the food to cook and most importantly doing the washing up!
**HANDY COOKING AND PREPARATION TIPS**

Eating more fruit and vegetables needn’t be difficult. You don’t have to be a master chef to get your family to eat more and you don’t have to spend any more money. You don’t even have to radically change your diet. Take a look at the following tips on how to get your whole family to enjoy fruit and veg – with minimum fuss:

1. **FRUIT SMOOTHIES ARE ANOTHER EASY AND FOR UPKEEP YOUR DAILY FRUIT AND VEGETABLE QUOTA, MISS LAMBERT FROM BIRMINGHAM AGREES:**
   “Put chopped pear, clementine, banana or any fruit in a blender with 3-4 fluid oz of milk and a tablespoon of natural yoghurt and make a smoothie. Absolutely delicious.” If you don’t have a blender, use soft fruit like bananas or strawberries, which are easier to mash.

2. **“My partner and children don’t leave the house in the morning without drinking a glass of fruit juice – at least they know they’ve already started on their 5 A DAY!”**
   **KIMBERLEY GORDON, BLACKPOOL**

3. **IF NONE OF THIS WORKS, BE A MASTER OF DISGUISE, LIKE MRS ELLIE GLENTON FROM NORTHUMBERLAND:**
   “Pureed vegetables can be added to sauces for pasta or spooned over mashed potatoes. Fruit can also be pureed to pour over ice cream, custard, puddings or added to milk for milkshakes.”

4. **OR TAKE CHILDREN’S FOOD WRITER, ANNABEL KARMEL’S ADVICE:**
   “If there is one food that almost no child (or grown-up for that matter!) can resist it must be an ice lolly. Try pouring fruit smoothies, fresh fruit juice or pureed fresh fruits into ice lolly moulds and freeze them.”

5. **TRY ROASTING VEGETABLES:**
   “Chop up red onions, courgettes, butternut squash and garlic. Pour a little oil over the vegetables and season. Cook for about an hour at 200°C. You can cook most vegetables like this but I recommend this combination. I could eat platefuls of this!”
   **MRS MARY DONOVAN, EAST YORKSHIRE**

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**WHAT COUNTS**

If you’re feeling inspired by the tips in this booklet but you’re unsure of what counts as a portion, use the following pointers to help you and your family reach your 5 A DAY target.

**AS A RULE, ONE PORTION OF FRUIT OR VEGETABLES IS EQUIVALENT TO 80 GRAMS**

**(APPROXIMATELY ONE HANDFUL)**

*1 MEDIUM SIZED PIECE OF FRUIT*

E.G. APPLE, BANANA, PEAR OR ORANGE

- Fresh, frozen, chilled, canned and dried fruit and vegetables all count.
- Potatoes, yam and cassava don’t count towards 5 A DAY because they are classified as ‘starchy’ foods.
- The following are examples of a portion:
  - 2 small satsumas or 2 plums
  - 12-15 cherries or grapes
  - 1 tablespoon of dried fruit such as raisins or chopped apricots
  - 1 slice (approx. 2 inches) of melon
  - 3 heaped tablespoonsful of cooked carrots, peas or sweetcorn
  - 1 cereal bowl of mixed salad
  - 7 cherry tomatoes or one medium-sized tomato
  - Half a pepper, one onion and three handfuls of sliced mushrooms all count as one portion.
  - 1 glass of 100% fruit (or vegetable) juice also counts as a portion — but you can only count juice as one portion — however much you drink in a day.

For further information about 5 A DAY, visit [www.dh.gov.uk/healthtopics](http://www.dh.gov.uk/healthtopics)
GETTING YOUR 5 A DAY

FURTHER TIPS

Most kids will enjoy helping you prepare meals from time to time. Encourage them to be involved; suggest they help you to make shapes out of vegetables, such as carrots, before they are cooked

ANNABEL KARMEI, FOODWRITER

“Put some prepared fruit and veg snacks, like sticks of pepper, in a container in the fridge with your children’s favourite cartoon stickers on to encourage your kids to eat them if they’re hungry between meals”

DR ROB HICKS, GP AND MEDICAL BROADCASTER

“Finely grate carrot and stir in to soups, mashed potato and stews”

MRS J CRAWFORD, WALSLEY

“Put grated vegetables and fruit in their sandwiches”

CATHERINE SHILTON, BEDFORD

“Liquidise vegetables in homemade tomato sauce”

MRS B AKKAYA, LONDON

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For further information about 5 A DAY, visit www.dh.gov.uk/healthtopics

NHS
Fuel for Living...

Recipes and ideas to help you reach 5 A DAY

What counts towards 5 A DAY?

- Fresh fruit, carried 100% juice and dried fruit and vegetables all count
- 1 portion is about a handful of fruit, a medium apple, banana, orange or pear,
- 1 portion of vegetables is 3 heaped teaspoons of cooked or 1 small salad
- Beans and other pulse vegetables, such as kidney beans, lentils and chick
- A medium-sized glass of 100% fruit or vegetable juice or smoothie counts
- Potato, sweet potato, or yam, which is not normally eaten with other food, also count as 1 portion of fruit and vegetables
- To get the most benefit, you should aim to include a variety of fruit and vegetables each day
- To get the most benefit, you should aim to include a variety of fruit and vegetables each day

To get a healthy balance, make sure that you eat a variety of at least 5 portions of fruit and vegetables a day.

www.5aday.nhs.uk

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Life in the fast lane

Eating well and cooking for yourself may feel like the last thing you want to do after a long day at work or college or a late night. But eating healthily doesn’t have to take loads of time or cost loads of money. Eating a healthy diet will give your body what it needs to help you keep up with your hectic lifestyle while helping to keep you fit and healthy — inside and out.

In putting this booklet together, we asked some of you what your favourite meals were — both to cook for yourself and to be cooked for you. Your top choices included spaghetti bolognese, curry and a traditional roast dinner with all the trimmings. So we’ve included quick, easy and healthy recipes for some of your favourite dishes for all sorts of situations, as well as tips on how to eat healthily when you’re out and about.

It’s recommended that we eat at least 5 portions of a variety of fruit and vegetables each day. They give you plenty of vitamins and minerals.

For example, many are naturally high in folate, vitamin C and potassium. Fruit and vegetables are also a good source of fibre and other substances, such as antioxidants. These are all important for your health.

Most fruit and vegetables are also generally low fat, low calorie foods so eating fruit and vegetables instead of foods that are high in fat and added sugars makes it easier for you to keep your weight within the healthy range.

In the longer-term, eating more fruit and vegetables may help reduce the risk of the two main killer diseases in this country — heart disease and some cancers.

This booklet will help you to fit more fruit and veg into your diet and hopefully make it easier for you to reach the target of at least 5 portions a day.

Fajita Fiesta

A great social meal needing surprisingly little preparation! Impress your friends with a Fajita Fiesta....

- Serves: 4  
- Preparation time: 15 minutes  
- Cooking time: 20 minutes  
- Cost per serving: £1.88  
- 5 A DAY portions per serving: 2

Get cooking

- Heat the oil in a large pan
- Add the onion and diced chicken and cook for 5 mins
- Add the remaining vegetables to the heat and stir
- Stir in the fajita mix
- Meanwhile prepare a mixed salad of tomatoes, cucumber and lettuce leaves
- Warm the tortillas in a heated oven for 3 mins or a microwave for 1 min
- Serve all together

(v) Couldn’t be easier... simply add more vegetables and ignore the chicken

Alternative ideas to jazz it up...

- Serve with a tomato salsa for extra flavour
- Provide carrot stick dips with hummus or guacamole as a starter to get you in the mood
- Use leftovers as a sandwich filler or with a baked potato

What you’ll need:

1 tablespoon olive oil
4 skinless chicken breasts (diced)
1 red, 1 green, 1 yellow pepper (chopped)
Handful of mushrooms (roughly chopped)
Packet of fajita mix
8 soft flour tortillas
1 chopped onion
Salad ingredients: tomatoes, cucumber, lettuce

Top Tip:

✓ If you’re less keen on the spice, serve with natural yoghurt

Did you know?

Red and yellow peppers have 4 times as much vitamin C as oranges
Easy curry

Nearly 1 in 10 of you thought curry would be the best meal someone else could cook for you... second only to the roast (see later). Here's a quick and easy way to impress your friends with their favourite food.

Food for friends
- Serves: 4
- Preparation time: 10 minutes
- Cooking time: 15-20 minutes
- Cost per serving: £1.75
- 5 A DAY portions per serving: 2

What you’ll need
2 teaspoons vegetable oil
1 onion, chopped
Some garlic
2 tablespoons curry paste
Selection of your favourite vegetables, chopped (e.g. courgettes, peppers, carrots, mushrooms etc)
1 large cooking apple, chopped
600ml vegetable stock
2 x 400g cans chopped tomatoes
Freshly ground black pepper

Get cooking
- Heat a small amount of olive oil in a large pan and fry the onion
- Add the vegetables and garlic gently for two minutes. Add the curry paste to the onion and cook for two minutes more
- Add tomatoes, stock and seasoning
- Add the vegetables and apple and bring to the boil
- Put the lid on the saucepan, reduce the heat and simmer for 15 minutes or until the vegetables are cooked. Serve with rice, naan bread, chapati or on top of a jacket potato

Did you know?
Your bones continue growing until your mid-20’s and the best way to make sure you build healthy strong bones is to make sure you get enough calcium in your diet. The richest vegetable sources of calcium are dairy products, dark green leafy vegetables, and beans. You can also get useful amounts from red kidney beans, soya beans, peas, broccoli, cabbage, celery and parsnips, dried apricots and figs

Top Tips:
✓ For meat lovers, add a little lean diced beef or diced chicken at step 1. Simply cook with the onions and garlic until browned. Remember! Meat takes longer to cook than vegetables, so you will need to increase the cooking time to about 30 minutes
✓ For a different meal, you could try adding about 2 cups of lentils to your liquid. Three tablespoons of lentils count towards 5 A DAY and are a good way to get more fibre into your diet
✓ There is no need to spend £1 a go on jars of curry sauce when you can spend the same on a jar of curry paste (along with a tin of tomatoes every time), which will make four or five curries
Perfect Pasta

Pasta is cheap to buy and simple to cook – and it will fill you up too! Here are some tasty sauce ideas to jazz up your pasta in an instant. The quantities aren’t that important in these recipes – just put in however much you like.

The following recipes:
- Serves: 1
- Preparation time: 10 minutes
- Cooking time: 15-20 minutes
- Cost per serving: £1
- 5 A DAY portions per serving: 1

Top Tips:
- Make a big batch of the basic tomato sauce – it will freeze well and could also be used to pour over vegetables or meat for a different meal
- If you have left over vegetables from a previous meal, simply add them to your basic tomato sauce. If you have a blender you can disguise the vegetables completely in the sauce
- You can easily add mince, diced chicken or other meat to any of these recipes if you want a change

Did you know?
According to the botanical classification, tomatoes are a fruit rather than a vegetable

Basic tomato sauce
- Chop an onion and gently brown in a saucepan in a little oil
- Add canned tomatoes (about one large can per person)
- Add black pepper to taste and some mixed herbs
- Bubble for about 10 min (keep stirring so it doesn’t stick to bottom of pan)
- Serve with a sprinkling of grated cheese

Roasted vegetables
- Preheat the oven to 180°C / gas mark 4
- Roughly chop vegetables of your choice into large chunks and place in an ovenproof dish or roasting tin. Most veg roast well – the only rule is the more the merrier!
- Drizzle a little olive oil and a sprinkling of mixed herbs over the vegetables and put them in the oven for about 30 minutes
- When cooked, heat up one or two tbs of chopped tomatoes and heat through on the hob
- When the pasta is cooked, mix in the roasted vegetables and tomatoes and season with some black pepper

Cherry tomatoes and basil
- Wash and halve a few handfuls of cherry tomatoes – or use normal tomatoes quartered
- Place in a saucepan with a little olive oil and cook gently over a low heat with a sprinkling of seasoning
- Roughly chop a few handfuls of basil – fresh is the tastiest but can be pricey – (if you’ve got a garden or window sill, you could grow your own!!) - dried basil or a couple of tablespoons of pesto are a good substitute for fresh
- Once the tomatoes have softened, add the basil to the pan. You could also stir in some other veg – like sweetcorn or sliced courgettes – and cheese – either mozzarella or parmesan are good with this
- Heat and serve

Garlic mushrooms, bacon and yoghurt
- Gently cook some chopped onions, button mushrooms and chopped bacon in a pan with a bit of oil
- Add some crushed garlic and cook until the onions and mushrooms are starting to soften
- Stir in a couple of tablespoons of low fat natural yoghurt
- Serve with pasta of your choice
The one pot roast

The roast came top of the list of meals that you'd like someone else to cook for you. So, to help you recreate a low maintenance version of your favourite Sunday lunch — any day of the week — with minimum washing up, here is a recipe and some helpful hints to make it extra special for your mates.

It's all in the timing...
- Serves: 4
- Preparation time: 20 minutes
- Cooking time: 40 minutes
- Cost per serving: £1.50
- 5 A DAY portions per serving: 3

What you’ll need
- 8 chicken pieces (thighs, legs, breasts — whatever you fancy)
- 5 carrots
- 3 parsnips
- 2 red onions, peeled
- 3-4 cloves garlic
- 2 tablespoons olive oil

And on the side:
- 4 potatoes (for mashing), peeled
- 1 small swede, peeled
- 2 teaspoons margarine
- 100ml hot milk
- 4 handfuls of green beans

Get cooking
- Preheat the oven to 200 degrees C / gas mark 6
- Put the chicken pieces in a large roasting tin
- Peel and chop carrots, parsnips and red onions (it doesn’t really matter how you do this — big chunks will make your dish seem more rustic) and add to the roasting tin
- Peel and crush the garlic and add to the tin or simply add the whole cloves
- Pour a bit of olive oil over the chicken and vegetables and put the whole lot in the oven
- Cook for around 40 minutes or until the juice runs clear when you put a skewer in the chicken pieces.

For the mash
- Peel and chop the potatoes and swede and put together in a large pan of boiling water for 20 minutes or until they are soft
- Drain the water from the potatoes and swede
- In the same pan (for minimum washing up) mash the potato and swede together with a little hot milk, a small knob of butter and seasoning

Why not?
- Add some green beans on the side — either steam them or add them to boiling water for a few minutes. They’ll brighten up your dish and add to your 5 A DAY
- Add some finely chopped spring onions or some chopped fresh herbs to the mash
- Serve the mash, chicken and vegetables all together

Juice it up
- To make real gravy pour the juices from the roasting tin into a saucepan (try to skim off any excess fat) and stir in about a tablespoon of flour. Once the flour is mixed in, slowly add about 2 cups of the leftover water from your vegetables and a stock cube. Bring to the boil then reduce the heat and simmer, stirring, until it starts to thicken

Did you know?
Parsons were first cultivated during Roman times. They were served as dessert with honey and fruit

Top Tip:
- Adding fruit and vegetables helps to ‘bulk out’ a meal without adding a lot of extra calories
Spag Bol

Spaghetti bolognese is an old favourite – our research shows it's one of the most popular dishes to both cook and eat with friends. Try this easy version of the well-known meal and get 2 portions of your 5 A DAY at the same time.

- Serves: 4
- Preparation time: 10 minutes
- Cooking time: 30 minutes
- Cost per serving: £0.33
- 5 A DAY portions per serving: 2 per serving

What you'll need

1 tablespoon vegetable oil
1 onion (chopped)
1 x 400g can chopped tomatoes
4 medium sized carrots (diced)
A handful of mushrooms, quartered
1 cup frozen peas or 1 small can peas
1 clove garlic (crushed or finely chopped)
2 pinches mixed herbs
400g extra lean mince or quorn (v)
2 tablespoons tomato puree
400g spaghetti (check packet for cooking instructions)
Freshly ground black pepper

Get cooking

- Heat the oil in a large pan
- Add the onion and garlic and cook for 2 mins
- Add the mince/quorn and cook over a high heat, stirring for a further 3 mins or until meat is brown
- Add the carrots and cook for 2 mins
- Add mushrooms, peas, mixed herbs, tomatoes and tomato puree, cover and simmer for approximately 25 mins

(v) For a mouth-watering vegetarian bolognese, add 4 cupfuls of red lentils to the pan instead of the mince. Lentils absorb lots of water so check the pan and add water if required.

- Boil spaghetti for 8 mins or according to the pack instructions – you could try the old trick of chucking a small strand of the spaghetti at the wall – if it sticks it's cooked!
- Drain the pasta and serve with your delicious sauce on top
- Serve with a side salad for extra health benefits

And there's more

Chill out

- Add a tin of kidney beans to the bolognese and a pinch of chili powder to transform it into an effortless Chilli Con Carne – best with rice or a jacket potato instead of pasta.

Lasagne

- Transform the bolognese sauce into a lasagne in an instant. You will need white sauce and lasagne sheets. Simply spread a layer of bolognese sauce on the bottom of a large oven dish, cover with a layer of white sauce and place a layer of lasagne pasta sheets on top. Repeat until you have built up two or three more layers and top with a little grated cheese. Cook it in a pre-heated oven (200°C/gas mark 6) for about 50 mins. Check the pasta is cooked and serve with a large side salad.

Top Tip:

- A small can of kidney beans counts as 1 portion of your 5 A DAY
It's Stir Fryday!

Get cooking:
- Only use ingredients according to the pack's instructions.
- While the rice is cooking, heat the oil in a large pan or wok. Add the red onions and colored chicken and cook.
- Add the remaining vegetables to the heat and stir. Add a large water and the soy sauce or stir fry sauce of your choice.
- Add the stock cubes in a cup of boiling water until used to the pan and heat for a few minutes.
- Clean the rice and serve with your delicious stir fry.

What you'll need:
- 1 tablespoon oil
- 1 onion
- 4 skinless chicken breasts (kissed)
- Selection of chopped vegetables – choose your own
- 2 tablespoons soy sauce or stir fry sauce
- Packet of bean sprouts – optional
- 200g rice

Top Tip:
- It's easy to confuse tater and burger – often when you think you're feeling hungry, your body actually wants fluid. A glass of fruit juice helps to re-hydrate as well as providing important nutrients.

Food on the run:
- If you're on a tight budget, cooking can be expensive and time-consuming.
- Go large on salads by picking it to your burger or kebab for you without having to ditch it altogether. Hand on to find out...
- Vegetarian takeaway – choose the large salads or wraps with lots of vegetables. Or go for a cheese or veggie burger.
- Use up some extra snacks or vegetables in the fridge to make a different meal. Use up the leftovers.
- If you're travelling, try to make as much use of salads or wraps as you can.
- Traditional tucker – if you're craving fish and chips, try some mushy peas on the side – they count towards 5 A DAY.
- Don't buy fruit or vegetables that are out of season. Wrap them to keep fresh.

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Burning the candle at both ends

1. Energy boost

If you’ve been working long shifts or burning the candle at both ends, the hours can mess up your body clock and leave you feeling flattened. One thing that will help to keep your energy levels up is to choose foods that release energy gradually.

Bananas or dried fruit like raisins or dried apricots provide a steady supply of sugar giving longer lasting energy. It can be tempting to go for high sugar foods that give you a quick blood sugar rush but this is quickly followed by a crash, which makes your energy slump.

Did you know?

Zinc helps the body heal wounds, which means that if you suffer from spots it’s important to eat plenty of foods rich in zinc to help your skin heal. Green vegetables, beans and pulses, figs and dried apricots provide useful amounts of zinc.

2. Exam fever

If it’s exam time and you need to concentrate hard on revision, here are some ideas to get some brain food into your diet:

- Make sure you’ve got enough iron in your body. A lack of iron can make it difficult to concentrate and shorten your attention span – not good news if you’re trying to revise. Green leafy veg like watercress or spring greens, broccoli and pulses (like kidney beans) and dried fruit such as raisins and figs are a useful source of iron.
- Vitamin C can also help you absorb the iron in your body, so have a glass of orange juice with your meal.
- When you’re stressed you’re more vulnerable to colds and other infections – eating plenty of fruit and veg, particularly those that are rich in vitamin C, will help keep your immune system strong.

3. The morning after the night before...

Feeling fragile? After a night on the town, many people crave fatty or high sugar foods. Here are some easy ways to help you beat off those unhealthy cravings and make you feel more lively:

- Eating foods that are naturally high in vitamin C can give your tired body a boost – oranges, grapefruits, kiwis and strawberries make great juices and smoothies and they have a high vitamin C content. Or try tomato juice as a good alternative to orange juice.
- Bananas are a particularly great cure after a heavy night as they help to satisfy the craving for sweet foods. Try putting a banana in your smoothie – it’s a great way to use up any fruit that may be overripe.

Drinking a lot can make you look bad, feel sluggish and won’t keep you on top form. To keep this from happening men should drink no more than 3-4 units of alcohol a day (a unit is a small glass of wine or half a pint of normal strength lager) and women should drink no more than 2-3 units. This is true for everyday drinking or when you’re out at weekends so you can’t “store up” all your units and use them in one go – that’s binging!
Snacking on fruit and veg like carrot sticks and strips of red pepper can keep hunger at bay and because both hot and cold low-fat, low-calorie foods.

Keep energised

Did you know?
The B vitamins are vital for energy production, keeping the brain, nerves, blood and muscles functioning and skin, nails and hair healthy. Some of the B vitamins are found in bananas, peas, beans, lentils and leafy greens.

Meals in a hurry

Whether you are rushing out or fed up after a long day, the thought of preparing a healthy meal from scratch can often be the last thing you feel like doing. But there’s a quicker, easier solution – ready meals which you can knock up in the same time it takes you or your partner to make a cup of tea and microwave a ready meal – and they’re cheaper too!

Keep frozen pizza keeps in the freezer. You can easily create a healthy and tasty pizza by topping them with tomatoes, onions, red or green peppers, and any other vegetables you like. Just make sure you cut them into four equal portions. Add your preferred sauce and take them out of the freezer just before you need them. Cut them and serve with a side salad and you’ve got a meal in minutes.

Close the egg and store it for up to three months. You can use these to make scrambled eggs, scrambled eggs or scrambled eggs. Scrambled eggs in the microwave or on the stove top will need to be cooked for an additional minute if you want to cut the calories and keep the reduced fat in the egg mixture. As the eggs heat up, they will cook, lift up the egg mixture and create a crumpled and fluffy texture. Once the egg is cooked, it will cool down and become soft, so have it at hand and serve it as a side dish.
One pot wonder

The best thing about this meal is that you can use whatever vegetables you have to hand. If vegetarian foods aren't your thing, just add some diced meat to the pot – whether it's chicken, beef or lamb. The ingredients below are just a guide.

- Serve: 4  - Preparation time: 15 minutes  - Cooking time: 1 hour
- Cost per serving: £1.30  - 5 A DAY portions per serving: 2

What you’ll need

- 2 medium onions
- 4 medium carrots
- 1 small swede
- 2 medium parsnips
- 2 medium leeks
- 1 clove garlic, crushed or finely chopped (you could cheat and buy some garlic granules or paste, or simply leave it out all together)
- 1 tablespoon dried mixed herbs
- 300ml vegetable stock
- 1 tablespoon plain flour
- 4 large potatoes, thinly sliced
- 1 tablespoon margarine
- Freshly ground black pepper

Get cooking

Step 1
- Preheat the oven to 190 °C / gas mark 5. Chop the vegetables into chunks and arrange in layers in a large casserole dish (except the potatoes). If you don’t have a casserole dish, you can put them into a saucepan and cook on the hob.
- Season the vegetable layers lightly with black pepper and sprinkle them with garlic and chopped herbs as you go.

Step 2
- Boil 300ml water and add the stock cube. Add the flour to the stock and pour over the vegetables.
- Arrange the potatoes in overlapping layers on top. Dot with a small amount of butter and cover tightly.

Step 3
- Cook in the oven (or on the hob) for about an hour, or until the vegetables are tender.
- Remove the lid from the dish and cook for a further 15 minutes until the top layer of potatoes is golden and crisp at the edges.
- Serve and enjoy!

Did you know?

You probably remember being told as a child that eating carrots would help you see in the dark – and it’s true - carrots are a good source of beta carotene, which our bodies turn into vitamin A, and vitamin A is important for night vision.

Top Tips:

✔ If you want to add meat to this meal, gently brown the diced meat first, then add to the casserole dish with the raw vegetables. The meat will be very tender if cooked slowly and will soak up all the flavours from the vegetables.
Bonza breakfast

Breakfast is the most important meal of the day. It provides you with energy for the day. And if you miss it, it’s not going to help you lose weight. Research shows that eating breakfast can actually help people control their weight. Here are some ideas to help you kick start your day.

Porridge
You can get a 1kg bag of porridge oats for well under £1, and a bowl of porridge is a really filling meal to start the day. The traditional Scottish way to make porridge is with water and a pinch of salt. If you’re not a fan of that, try making it with milk and a teaspoon of honey. Add a sliced banana or some other fresh or dried fruit for variety.

Bananas
- If you really can’t face eating anything in the morning, blend up a banana with some milk and yoghurt to make a healthy smoothie. Try adding a tablespoon of peanut butter to boost protein levels
- Bananas contain dietary fibre, which helps to keep your digestive system working well. Bananas are a firm favourite with sportsmen and women because they contain slow release carbs which help to boost energy levels
- If you haven’t got time for a proper meal, a banana sandwich makes a quick and healthy snack
- Bananas are rich in potassium which can help lower blood pressure

Full English
An old time favourite and a great way to get veg into your breakfast. Add baked beans, 3 tablespoons of cooked mushrooms and a tomato and you’ve already ticked off 3 portions. Grill it rather than fry it for the lower fat option.

Did you know?
Breakfast can provide you with 25 percent of your daily nutrients. Eating a healthy breakfast can help boost your mental and physical performance throughout the day.
Sneaky Snacks

Revitalise your brain and your body with a 5 minute snack break. Here are some ideas to make sure your snack hits the spot:

- If you can’t stomach breakfast in the mornings, just take a banana with you in your bag and eat it during the morning to kick-start your morning metabolism. Sports enthusiasts rely on this potassium-packed high energy fruit which will help keep your hunger pangs at bay until lunch.
- Dried fruits provide a steady supply of sugar giving longer lasting energy.
- No preparation time? Just heat up a can of baked beans with toast or a jacket potato for lunch and tick off another 5 A DAY portion.
- Chopped apple and yoghurt can refresh and boost your energy levels in the middle of the day.
- Carrot sticks or slices of pepper are excellent snack foods and can hold off hunger during the day.
- Smoothies are an easy way of upping your fruit intake. If you don’t have a blender you can just mash the softer fruits like strawberries and bananas.
- Try keeping a supply of cherry tomatoes or easy peel fruit in your desk drawer or bag and snack on these instead of eating chocolate or crisps.

Top Tip:

✔️ The secret to healthy snacking is to choose your snacks wisely – fruit (fresh, canned or dried) is a great choice. Try keeping a small bag of dried fruit in your desk at work or in your bag so you’ve always got a healthy snack at hand when you need one. Fruit smoothies or raw vegetables served with hummus or guacamole are another healthy choice.
Write down your own recipe ideas

Name of recipe:

Ingredients:

How to make:
Physical activity

What's in this section?

- Why is physical activity important?
- What is the recommended amount of physical activity that we should take?
- Becoming more physically active?
- Local resources to help you become more active!

Why is physical activity important?

Modern lifestyles are often much less active than those of our parents and grandparents and many of us now have very low levels of physical activity. Getting enough exercise can have advantages for both our physical and mental health. Staying physically active helps to prevent us from becoming overweight and will reduce our chances of developing up to 20 chronic diseases including:

- Heart disease
- Having a stroke
- Diabetes
- Certain types of cancer
Regular physical activity also helps us to feel good about ourselves and has been shown to reduce stress and help with problems such as anxiety and depression.

So there are many reasons for developing a physically active lifestyle but perhaps one we also shouldn’t forget is that it can be fun! Staying physically active doesn’t have to about gruelling sessions at the gym it can be doing things we enjoy such as playing sport, gardening or taking walks in the countryside. Hopefully in this section we can help you decide what type of physical activity you would most enjoy participating in.

What is the recommended amount of physical activity that we should take?

The department of health recommend that in order for adults to remain fit and healthy and control their weight they should take:

- A total of at least 30 minutes of at least moderate intensity physical activity a day, on 5 or more days a week.

Moderate physical activity includes doing things such as walking, decorating, doing housework and playing sports such as golf or badminton.

However, adults who have a high energy intake should aim to take 45-60 minutes’ of activity each day may be needed in order to prevent the development of obesity and people who have been obese and who have lost weight may need to do 60-90 minutes of activity a day in order to maintain their weight loss.
How much physical activity do you currently take?

Most of us are probably unaware of how physically active we are. In order to find out how active you are you might want to consider completing the physical activity diary on the next page. Just record the activity you take part in and how long you do each activity for, and remember this should include day to day activities such as walking or cleaning the house as well as more rigorous activities like cycling or jogging. To illustrate how to fill in the diary we have completed some activities on Monday for you, but if you need any extra help you can always ask your STR worker for assistance.
<table>
<thead>
<tr>
<th>Monday</th>
<th>Afternoon</th>
<th>Evening</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Walked to shops &amp; back – 15 minutes</td>
<td>Played football – 60 minutes</td>
</tr>
<tr>
<td>Tuesday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wednesday</td>
<td></td>
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<td>Thursday</td>
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<td>Friday</td>
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<tr>
<td>Saturday</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sunday</td>
<td></td>
<td></td>
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</tbody>
</table>

Activity diary
Becoming more physically active?

In section 5 of this booklet we will explore some ways of beginning to develop a healthier lifestyle. First lets think about some of the principles that might be important in identifying activities that you will want to participate in both now and in the future.

- **Physical activity should be fun. If it is fun, you are more likely to continue with it.**
- **You can become more active when completing routine, everyday activities, for example by walking to the shops rather than taking a bus.**
- **Activities that we have previously enjoyed are more likely to be enjoyed again in the future.**
- **Activities that give us a sense of achievement may be likely to be continued.**
- **Doing activities with friends can be more fun than doing them on our own.**
- **Your 30 minutes of moderate physical activity can be built up through the day and not all at one time. So 5 minutes climbing stairs instead of taking the lift will make up a sixth of your required activity that day.**

To help you think about some activities that you might want to think about taking part in, we have provided a list. You will see that there are activities that you could do on your own as well as ones with other people.
<table>
<thead>
<tr>
<th>Things you can do on your own</th>
<th>Things you can do with a friend</th>
<th>Things you do in teams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>Walking</td>
<td>Badminton</td>
</tr>
<tr>
<td>Rambling</td>
<td>Rambling</td>
<td>Bowls</td>
</tr>
<tr>
<td>Dancing</td>
<td>Dancing</td>
<td>Cricket</td>
</tr>
<tr>
<td>Swimming</td>
<td>Swimming</td>
<td>Football</td>
</tr>
<tr>
<td>Golf</td>
<td>Golf</td>
<td>Rugby</td>
</tr>
<tr>
<td>Cycling</td>
<td>Cycling</td>
<td>Hockey</td>
</tr>
<tr>
<td>Fitness training</td>
<td>Fitness training</td>
<td>Ice Hockey</td>
</tr>
<tr>
<td>Ice Skating</td>
<td>Ice Skating</td>
<td>Netball</td>
</tr>
<tr>
<td>Martial Arts</td>
<td>Martial Arts</td>
<td>Martial Arts</td>
</tr>
<tr>
<td>Trampoline</td>
<td>Table Tennis</td>
<td></td>
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<tr>
<td>Running</td>
<td>Tennis</td>
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<tr>
<td>Jogging</td>
<td>Running</td>
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<tr>
<td>Track events</td>
<td>Squash</td>
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<tr>
<td>Gym</td>
<td>Jogging</td>
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<tr>
<td>Yoga</td>
<td>Track events</td>
<td></td>
</tr>
<tr>
<td>Tai Chi</td>
<td>Gym</td>
<td></td>
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<tr>
<td></td>
<td>Yoga</td>
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</tr>
<tr>
<td></td>
<td>Tai Chi</td>
<td></td>
</tr>
</tbody>
</table>
Local resources to help you become more active!

Lancashire
Burnley & Pendle

Blackburn & Darwen

Preston
http://www.preston.gov.uk/leisure-and-culture/leisure-and-sports-centres/

Blackpool
http://www.blackpool.gov.uk/LeisureandCulture/SportandPhysicalActivity/

Lancaster
http://www.lancaster.gov.uk/Category.asp?cat=491
Merseyside

Liverpool

http://www.liverpool.gov.uk/Leisure_and_culture/Sports/index.asp

Sefton


Knowsley

Here are some other really useful links to national sites that you can search locally:

http://www.activeplaces.com/

This website allows you to search for sports facilities anywhere in England. Very useful!

http://www.sustrans.org.uk/

This site helps you to find walking and cycle routes near to you. This is great for people wanting to walk or cycle to work or the shops etc and it has a great downloadable map that shows all the routes.

http://www.runtrackdir.com/

This lists all the athletic and running tracks alongside the UK Athletics Club Website Directory.
5. Getting started

Okay, so now we have some information about what a balanced diet is, and why it’s so important for us all. We have also considered the huge benefits of having a physically active lifestyle. Now we can turn to you and consider what you want to do with all this information. We have designed this book to work alongside your sessions with your STR worker and to support you as you take steps towards achieving your diet and activity goals.

Your STR Worker

Your STR worker understands about some of the problems such as tiredness and poor motivation that often make it more difficult for people with mental health problems to maintain a healthy lifestyle. Your STR worker has also received specific training about healthy living.

Your STR worker’s role is very much like that of a personal fitness trainer. They are here to support and help you to decide what changes you would like to make to your diet and exercise level. Together you will set goals and make action plans for how you would like to go about changing your lifestyle and making these changes part of your everyday life.
Your STR worker will help you to consider the information about healthy eating and physical activity. Together you will plan changes to your lifestyle. Your STR worker will encourage and support you and help you to get over any worries or concerns you may have if the going gets tough.

You

You are the most important person here. Only you know what you eat and how much activity you take at the moment. Only you know what changes you would like to make. Most importantly, it is up to you what kind of change and how much change you make.

But you are not alone. During your individual sessions, you and your STR worker will make goals and plans. Bring along a family member or friend to your sessions if you want to, or ask your STR worker to talk to them on the phone about your goals and plans. You can also join in with the healthy living group sessions. The other group members are people, like you, who are trying to make changes to their daily diet and activity levels. Section 8 tells you more about these groups.
Remember healthy living is important for us all. Many of us struggle from time to time to keep up a good diet and stay active. All of the things suggested in this booklet are things that we also aim for.

**Your Friends and Family**

For most of us, our friends and families are usually the people we are closest to. Making changes in our lives affects not only ourselves but also those around us. Having the support of our friends and family is vital to making changes and keeping going.

This is especially true with changes to what we eat. We often need the help and support of the people we live with. We would very much like to include a member of your family or a friend to help you with making changes to your lifestyle. Talk with your STR worker about this. You may want to bring along a family member or a friend to your sessions. Or, you may want your STR worker to talk with your family or friend on the telephone about what you are doing and how they can help you. If you do not want anybody involved then that’s fine - just let your STR worker know.

For some people, they may find it helpful to have a family member or a friend join them in making changes to their
lives. Your family member or friend may even want to make changes themselves? We would encourage you to talk with your family or friends about your ideas on healthy living and the changes you want to make.

**SESSION 1 – SETTING GOALS**

Often people have some things about their lives that they know may be bad for their health and they would like to change. This may be that they eat a lot of junk food or don’t exercise regularly. During your first session with your STR worker you will have time to talk about the kinds of things you want to do and the changes you want to make to your lifestyle. Please use the spaces below to jot down any ideas you want to discuss.

**Ideas about what I want to achieve.**
How do I change my behaviour?

Once you have had time to consider the sort of things you want to achieve, you and your STR worker will start to write down some goals. Health experts tell us that in order for us to change one of our behaviours, such as eating more fruit; we have to firstly see the point in doing that, and secondly want to do it. The next stage involves making a plan. These plans are based on goals that you set for yourself with help from your STR worker.

By setting goals you will have something to aim for and will be able to measure how well you are doing. For each part of your diet or exercise you want to change, you can make goals. These goals will change over time. Once you have reached your first set of goals you can then make some more until you are happy with your own healthy lifestyle. It is important to remember that when you set yourself goals, be kind to yourself:

- Any change towards your goal is good, no matter how small
- Set yourself goals you can manage and build up towards the longer term goals
- Wait until you feel comfortable with your most recent change before you move onto your next goal
- When you achieve a goal, reward yourself
Sally wants to lose some weight and would like to become more active, but finds it difficult to stick to a plan. She thinks that eating more fruit is a good first step to helping her to lose weight. In addition, she thinks that eating more fruit will help her to be healthier. Sally is now on the way to beginning to change her behaviour. The most important thing Sally needs now is to decide that she really wants to eat more fruit then set herself some goals.

An example of some goals Sally might make are:

1) To eat a healthier diet by ensuring that I eat at least 5 portions of fruit and vegetables daily.
2) To be able to reach a target weight of 10 stone in 3 months
3) To be able to plan a weekly menu to ensure I eat healthily
4) To walk to and from work 4 times a week
What are your goals?

We have provided some sheets for you to write them down. Your STR worker will help you with this. Working with too many goals can be confusing. We would advise you to work with between one and three goals. Here is some advice for setting your goals:

- Ask yourself what you want to be able to do
- Be as specific as you can by stating how often you want to do something
- Set realistic goals, things you want to do in the future or used to do in the past
- State goals positively, start with ‘to be able …’ rather than ‘to stop …’ e.g. ‘to be able to eat 5 portions of fruit and veg daily...’ rather than ‘to stop eating junk food every day’

Goals are things to aim for. Pick things that will help you to achieve a healthier lifestyle. So that you know how you are doing, we have written down a simple scale underneath each goal. Circle one of the numbers for each goal. This will tell you how difficult you find each goal.

At the moment, you should choose goals that you want to aim for. As you do work with this programme the goals will become easier to achieve. Re-rating them every now and then using the same scale is an excellent way to monitor your own personal progress. Aim to do this at least monthly with your worker.
# My healthy living Goals

**Today's date**.................................

**Goal number 1**

.................................................................................................................................
.................................................................................................................................
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I can do this now (circle a number):

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Not at all     Occasionally           Often            Anytime

**Goal number 2**

.................................................................................................................................
.................................................................................................................................
.................................................................................................................................

I can do this now (circle a number):

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<th>4</th>
<th>5</th>
<th>6</th>
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</thead>
<tbody>
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</tr>
</tbody>
</table>

Not at all     Occasionally           Often            Anytime
Goal number 3

I can do this now (circle a number):

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<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>Occasionally</td>
<td>Often</td>
<td>Anytime</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6. Getting going – putting your plan into action

Like Sally who set herself some goals to aim for, you now need to make a plan for how you are going to achieve your goals. You know what you want to do. Now you need to say how you are going to do it.

Session 2 – MAKING A PLAN

The purpose of session 2 is for you and your STR worker is to make an ACTION PLAN for how you are going to achieve your goals. You will do this by writing down the steps you need to take to achieve your goals.

Your STR worker will ask you lots of questions about the best way of achieving your goals. Some of the questions may be:

1. Do you want to go swimming on your own or with a friend/family member?
2. Do you want your STR worker to accompany you for the first few times?
3. Are there any local swimming baths?
4. How much does it cost to go swimming and can I afford to go weekly?
5. Is there anything that would stop me going swimming?
6. What time of day is best?
All of these questions will help you and your STR worker to make an ACTION PLAN. Your Action Plan will include a series of actions or steps that you need to do. The action plan helps us to remember what we need to do, when we should do it, and where. It’s like posting a letter. If you want to post a letter you are much more likely to do it if you’ve decided when you’ll post it, where you’ll post it and how. You can use the spaces below to write down your action plans.
Here is an example:

<table>
<thead>
<tr>
<th>My Action Plan</th>
<th>Actions and by whom</th>
</tr>
</thead>
<tbody>
<tr>
<td>To go swimming 3 times per week</td>
<td>Identify the cost and distance of the local swimming pool (STR worker will do on Monday as well as seeing if there are any discounts that I am entitled to and tell me at my next session) (STR worker)</td>
</tr>
<tr>
<td></td>
<td>Ask my friend (Tom) if he will come with me on a regular basis ) I will ring him tonight (Me)</td>
</tr>
<tr>
<td></td>
<td>I don't have any swimming trunks that fit me (I am fairly sure that my mum will buy me them but I need to check) (Me)</td>
</tr>
<tr>
<td></td>
<td>My best time to go swimming is around lunchtime (before I go to work) STR worker to find out specific opening times of the pool to make sure it fits in with work (STR worker)</td>
</tr>
</tbody>
</table>

Your STR worker will provide you with blank action plan sheets. Use these to make up your own action plans along with your STR worker.
Session 3, 4 and 5 – Carrying out your action plan

During these sessions you will have the time to talk with your STR worker about how things are going.

Talk about the actions and steps in your plan that you have managed to do.

Talk about the things that you have not been able to do.

Talk about the problems that have got in the way.

Talk about what you can do about these problems.

Your plans may need adjusting. It may be that together, you need to change some of the steps or break them down into smaller steps to begin with. Use the action planning sheets your STR worker provided you with to make any further changes you want to.
Session 6 and 7 – Reviewing your progress

In these sessions you and your STR worker will look back at your original goals. Together you will get a sense of whether you feel you have achieved those goals and whether you think they have become part of your everyday life.

During these sessions you may find that there are things that have got in the way of you managing to achieve your goals. Use this time to problem solve with your STR worker. Think through solutions to these problems. You can then make some more action plans.

Also, during these sessions you can tell your STR worker what you think about the healthy living programme so far. What have you found helpful? Has anything been unhelpful? Could some things have been done differently?
7. Keeping Going

How do you keep any positive changes that you have made to your lifestyle going?

You have done really well so far. You have:

1. Thought about the current advice on healthy diets and exercise.
2. Set yourself some goals and made plans for how to achieve those goals.
3. Started to make changes in your life, by putting your plans into action.

The challenge now is the final stage which is to try to keep going with those positive changes. This can at times be difficult. At times you may well find yourself slipping back into your old behaviour. This is very common. But it is okay, it doesn’t mean you are back to square one and that all your hard work has been undone. Just go back to your goals once you are ready.
Session 8 – keeping up the good work

During this time, you and your STR worker will examine how far you have managed to stick to your goals and make them part of your everyday life. Together you can explore any barriers or changes to your life that mean it is now difficult to keep to your original goals.

Most importantly this session is about how your STR worker can help you to keep up the good work. You’ve done so well making changes to your lifestyle. Use this time to plan how you can keep those changes in your life.
Top tips for keeping up the good work.

1. Change is not immediate: It takes about 6 weeks to see progress and make a change more permanent.

2. Be persistent: It’s always harder to begin with, but making a plan will help you to keep going. If things are tough, you can always break steps in your plan down into further mini-steps.

3. Keep the reasons for your hard work close at hand. Keep reminding yourself that eating healthily and exercising is making a difference to your health right now as well as for the future.

4. Go back to your goals and action plans as soon as you can and pick up where you left off.

5. Did anything get in the way of you sticking to your plan – if so try to find a solution, so that you can go back to your plan.

6. Reward yourself for going back to your plan.
7. Don’t punish yourself for straying from your plan.

8. Does anything help you to stick to your plan – such as encouragement from others – if so, ask them to help you.

9. Keep a weekly log of how you are doing and what achievements you’ve made. Monitoring yourself is the best way to keep going.

8. **The Healthy Living Groups**

In addition to the individual sessions a range of optional healthy living groups will be taking place locally. These will be delivered by your support time recovery worker and a current or ex-user of mental health services. These groups will aim to incorporate some of the following ‘team exercise games’, lunch groups involving cooking and eating a healthy lunch, country walks, etc. Families and carers are more than welcome to attend the groups.
Appendix 4  The InterACT trial support, time and recovery worker training guide

HEalthy Living and Prevention of Early Relapse

Healthy Living Stream- INTERACT

Training manual

Karina Lovell, Alison Wearden, Tim Bradshaw and Diane Escott
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Introduction to the Helper study

Firstly I would like to thank you so much for agreeing to deliver this intervention. Your help is invaluable in the delivery of this study. Much of what is covered in this manual is provided in the training; however this manual is for your reference throughout the study.

How to use this manual

This manual is for you to use in delivering a Healthy Living Intervention with participants from the early intervention service. The manual is divided into the following sections

- Section 1 – What is this study about
- Section 2 – Delivering the intervention
- Section 3 – Supervision
- Section 4 – Monitoring
- Section 5 – Trial procedures

However if there is anything you do not understand or if you want to know more about the trial please contact us either by telephone or email

Karina Lovell (University of Manchester)

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University Place, Room 6.322a
University of Manchester
Oxford Road
Manchester, M13 9PL
What is this study about?

The study is funded for 5 years by the National Institute for Health Research (NIHR) and is led by Professor Max Marshall and the team includes Professor Shon Lewis, Professor Karina Lovell, Mr Jeff Warburton, Professor Graham Dunn, Professor Helen Lester, Professor Christine Barrowclough, Dr Richard Drake, Dr Linda Davies, Dr Fiona Lobban, Dr Nusrat Husain & Dr Alison Wearden. The overall aim of this study is to develop three phase specific interventions to prevent relapse of psychosis and or deterioration in physical health in people who are experiencing first episode psychosis. The three interventions which we are looking at are:

- Healthy Living intervention focussing on diet and exercise.
- Motivational Interviewing & CBT for substance misuse.
- Cognitive Remediation (CR) to improve insight & enhance CBT.

There are 3 streams of this research all with different teams and with different questions. This stream is concerned with the **Healthy Living intervention** and focussed on diet and exercise (if you would like more information on the other streams please do ask us).
Section 1

What is the Healthy Living Intervention about?

Let me introduce you to the trial team

Max

Professor Max Marshall. Max is a Professor of Community Psychiatry and is the principal investigator for Helper study and oversees all 3 streams.

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Karina

Karina Lovell leads the Healthy Living Stream and is a Professor of mental health at the University of Manchester. She is a mental health nurse by background, trained CBT therapist and provides low intensity interventions in the voluntary sector.

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Alison Wearden is a Health psychologist with an interest in the management of chronic illness, and experience of carrying out exercise and lifestyle interventions.

Alison Wearden

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Tim

Dr Tim Bradshaw is a senior researcher and lecturer in mental health nursing. At the university Tim works on a course which teaches multi-disciplinary groups of mental health professionals about psychosocial interventions

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Diane

Dr Diane Escot is a researcher is a research assistant to the Healthy Living Stream. She has a background in Psychology and works as a researcher in the School of Nursing, Midwifery and Social Work at the University of Manchester.

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Jeff

Jeff Warburton is the manager of the early intervention service and deputy Network director of the Camhs / EIS / SMS services for LCFT; he is a nurse by background with many years experience as a CPN and manager in AOT and EIS. His main role in the Helper program is to ensure the delivery of the research within the EIS whilst ensuring that effective care is delivered as usual to all service users, families and staff work to cooperate within the research.

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Nusrat

Dr Nusrat Husain is a psychiatrist and Senior Lecturer at the University of Manchester and an honorary consultant psychiatrist with Lancashire Early Intervention services. His area of research is mental health of ethnic minorities and developing culturally sensitive interventions. His role in this trial is to ensure that the interventions are culturally sensitive to the participants of South Asian origin.

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What is the Healthy Living Intervention study about?

The main aim of the study is to develop and test evidence based, acceptable and feasible healthy living intervention for people with first episode psychosis.

Rationale for the study

The life expectancy of adults with schizophrenia is reduced by about 15 years when compared with the general population (Hennekens et al 2005), and while some of this premature mortality is accounted for by suicide, approximately 62% of all deaths are attributable to natural causes (Harris and Barraclough, 1998). Adults with a diagnosis of psychosis are twice as likely as members of the general population to suffer from ischaemic heart disease, stroke, hypertension, epilepsy or diabetes by the age of 55 years (Hippisley-Cox & Pringle, 2005).

This poor physical health may be explained both by the side effects of antipsychotic medication (Marder et al, 2004) and by the unhealthy lifestyles that many individuals with psychosis lead (Brown et al, 1999). People with psychosis have been shown to take less exercise (McCreadie, 2003), eat poorer diets (McCreadie et al, 1998) and to be significantly more likely to smoke (Brown et al, 1999) than members of the general population. They are more likely to be obese (Homel et al, 2002) and show a higher prevalence of metabolic syndrome (Sacks, 2004) and diabetes mellitus (Bushe and Holt, 2004). Patients taking second-generation antipsychotics, which are frequently prescribed to control symptoms of psychosis, are at particular risk of weight gain (Green et al., 2000). The risk of antipsychotic induced weight gain may be even higher among young people experiencing a first episode of psychosis (Zipursky et al., 2005). Despite these findings a systematic review published by Bradshaw and colleagues in 2005 was only able to identify sixteen studies that had evaluated health education interventions for this client group and recent guidance from the Department of Health (2006) has highlighted the need to develop and evaluate health education programmes for this client group.

Despite the increasing evidence base, there remains ambiguity concerning the exact nature of the components of a healthy living intervention for people experiencing first episode psychosis including the specific content of the intervention, the delivery style, where the intervention should take place and the skills and expertise required to deliver the intervention. In addition to these components it is also important to develop an intervention that is acceptable
to those receiving the intervention and those who are delivering the intervention.

The study

Our overall aim is to develop and evaluate an evidence based, acceptable and feasible healthy living intervention for people in the early intervention service. There are two phases to our study.

Phase 1: Development of an evidence based, acceptable, feasible and culturally sensitive healthy living intervention by identifying key components

Phase 2: To test the intervention using an exploratory randomised control trial (RCT)

Phase 1 and 2

We completed 5 pieces of work to achieve our aim of producing a ‘top down’ ‘bottom up’ approach to develop an evidenced based, feasible and acceptable intervention (Figure 1) which included the following studies 1) a systematic review and meta regression 2) qualitative interviews with users experiencing first episode psychosis 3) focus groups/interviews with health professionals 4) core dimensions of the Self Regulatory model which is the theoretical model underpinning the entire HELPER programme 5) core components of culturally sensitive intervention. We then held a one day synthesis day where we put all this information together and developed the intervention. To make sure that we had done this correctly we then asked carers, health professionals and users what they thought of our proposed intervention.

We then wrote the intervention, prepared the training materials and trained the people delivering the intervention. We then wrote the protocol for testing the intervention. The results of the development work and the trial protocol will be explained in the training but if you would like more details of the aims, methods and results of this work then it is available in the Helper (phase 1 report which any of the trial team will let you have).
Figure 1: Development of the Healthy Living intervention

- Systematic review
- Qualitative interviews
- Qualitative interviews
- SRM model
- Synthesis
- Cultural issues
- Stakeholder group to formulate acceptable and feasible delivery of intervention
- Development of an evidence based, acceptable and feasible healthy living intervention
Section 2 – Delivery of the intervention

Your role

Your role in the trial is to deliver the Healthy Living Intervention.

In terms of the research trial we will be asking you to record all (or as many as possible treatment sessions), keep detailed records of session length, number of sessions and content, and to participate in supervision.

Our role (Karina, Alison, Tim, Max, Diane, Jeff and Nusrat)

Our role is to execute the trial using the most rigorous methods possible, and ensure ethics and research governance procedures are adhered too. We will be conducting all of the assessments (by this I mean eligibility for the study and outcome measures,) and providing you with support and supervision.

What is the intervention?

The Healthy Living intervention will comprise of 8 individual sessions over a 12 month period with an emphasis on facilitating participatory exercise and dietary change through the development and implementation of patient led action plans. These sessions will be delivered by a STR worker who will be trained in the delivery of the intervention. To facilitate implementation of exercise and dietary change a range of optional active group sessions will be offered by the STR worker for those who prefer a group based activity. To optimise engagement, choice and self management a booklet will be given to all participants providing educational advice, action plans, goals, details of the group sessions, healthy eating recipes on a budget etc. A strong emphasis will be placed on maximising carer/family engagement. The duration of sessions will range from between 30 minutes to an hour depending on individual need.

Delivering the intervention

This is a step by step guide to help you in delivering the intervention. Brief details of what should be included in each session are described in the ‘session review box’ and are followed by a more detailed explanation.
Session 1 – Introduction to the intervention and identification of health beliefs

Session 1 overview:

Orientation to the session

Orientation to the intervention (including participant’s role, your role, the patient book & the role of family and friends)

Assess lifestyle and elicit health beliefs

Identify and agree individualised goals

Offer choice and options of the scheduled groups

Ending: Feedback on session – final questions – next appointment

To help you with this session a crib sheet (interview guide) has been devised by the team to help you with this session and can be found in Section 6.

Orientation to the session

Introduce self, role (i.e. I am a Support Time Recovery or STR worker for short which means that my role is to work in partnership with you in helping you to maintain a healthy lifestyle. Confirm the patients full name, identify the purpose of the interview, and approximate duration of the interview, and recheck consent for the interview to be recorded. The extent of confidentiality should be explained.

Orientation to the intervention

- Role of the STR worker
- Role of the client
- Role of the book
- Role of friends and family
Role of the STR worker: You need to explain your role i.e. STR working on this research study. Your role is work in partnership to help to develop a healthier lifestyle by looking at and making agreed changes particularly in relation to diet and exercise. Emphasise that the key role is to support and monitor participants to implement real changes in their life style and to help people incorporate such changes into their everyday routine. It is also to emphasise that the participant is the ‘agent of change’ (i.e. they are in charge of their treatment). A way of explaining this to patients might be to use an analogy of a personal fitness trainer. You might introduce this by saying that a way of explaining your role is similar to a personal fitness trainer- “If you go down the gym or play sports, fitness trainers don’t do the actual physical work of getting you fit. That’s up to the individual. However, the trainer helps you to devise a fitness plan, monitor your progress and keep encouraging you when the going gets tough. I will act in the same way. I am there to support, advise, encourage and monitor your progress”. You will see participants for 8 sessions over a 12 month period, 5 sessions in the first 3 months, 2 sessions in months 4 and 6 and a final session in months 10 to 12.

Role of the participant: Explain the role of the participant – ie that it is a collaborative intervention, where they will work in partnership with you to try to make changes to improve their health through dietary and exercise changes. It is important to emphasise that the participant is the ‘lead’ in their intervention.

The Book

Introduce the book ensuring you tell the participant how to use it and what it contains. The book provides information on recommended diet and exercise, information about local activities which you may want to join, it provides information on some optional groups we are running and it also provides some practical information on ‘healthy living on a budget’ and a range of healthy recipes which you and or your family may want to try.

Your friends and family

We know how important friends and family are to people and we would very much like to include a member of your family or a friend to help you with making improvements into your life style. We will only do this with your permission but if you would like to bring a family member or a friend with you we would welcome this. Alternatively if you would like us to speak with a
member of your family or a friend on the telephone then we can do this as well. If you do not want anybody involved then just let us know.

Assess lifestyle and elicit health and cultural beliefs

It is important to conduct a patient centred assessment to elicit the participant’s health and cultural beliefs to ensure that their healthy living intervention is individualised and tailored to the participant’s life.

Introduce the assessment with an opening statement – e.g. “What would be helpful now is for me to understand more about you and your current and past lifestyle?” Try to use general open questions, specific open and closed questions to funnel the information into a clear formulation.

The interview should be flexible and responsive to the participant’s answers but sample questions which you may want to use are below.

Elicit expectations

Explore participant’s expectations of the intervention. For example “Tell me why you are interested in healthy living? (This may because they recognise that they are leading an unhealthy life style – or that they have put on weight due to medication, or it might be that previous exercise and dietary regimes have decreased since a relapse or it might be that they want to help other people – whatever the reason(s) this is a good lead in question to assess individuals own motivation and expectations of what they are seeking from the intervention.

Eliciting and working with beliefs about weight gain

The aim is to find out what the service user thinks about the whole issue of weight gain. By understanding what the service user thinks, you can start to see what is motivating his or her behaviour (or lack of behaviour!). Sometimes people’s beliefs may be based on lack of knowledge or misunderstandings, sometimes they may simply be unhelpful with respect to the behavioural goals. By discussing what the service user believes with him or her, you can encourage him/her to consider different ways of looking at the issues, which might be more helpful in the long run.
You can elicit these sorts of beliefs by

- Using a simple questionnaire such as an adapted version of the Brief Illness Perception Questionnaire (which we will provide)
- Asking specific questions, like “Why do you think you have put on this weight – what has caused the weight gain?”
- Asking people to talk about their experiences of trying to control their weight (for example) and then picking up on beliefs as they emerge, and discussing them (this needs a bit of practice)

The self-regulatory model says that people’s beliefs about a health threat (in this case weight gain) come from a variety of sources including their own experience, what they see happening with others (e.g. family members), what they pick up from the media, and what medical practitioners tell them. So when trying to understand a person’s beliefs about weight gain, it is important to consider these beliefs in the whole social context – ie what are the other people in his/her family like, does s/he have a history of dieting etc.

We know from research that there are a number of different aspects (or dimensions) of people’s beliefs about risks to their health. A very important one is **cause**. You need to know what the service user thinks causes people to gain weight in general, and what causes him or her to gain or lose weight. Why does she weigh what she does right now?

Examples of things that people may believe about their weight include:

- Everyone in my family is fat, it is all genetically determined;
- I have a particularly inefficient metabolism;
- I am overweight because I eat too much junk food;
- I am naturally very thin because my body burns up food more efficiently than other people’s.

Try to get a discussion going about the possible causes of weight gain, and take the opportunity to gently correct any misunderstandings, by suggesting alternative ideas.

Of course, we can’t pretend to have a perfect understanding of what determines a person’s weight – but a very good rule of thumb is that it is the result of the balance between energy in (food) and energy out (activity). When a person’s weight is stable, this is because they are managing to achieve a
balance between what they eat and what they do. It’s actually amazing how well most people achieve this balance, without thinking about it, by using a combination of bodily cues (feeling hungry or feeling full up after eating, wanting to get out and do something, or the feeling of needing to rest) and external cues (having a habitual portion size for your morning cereal; knowing how much to prepare for a family meal; playing football on a Friday night with your mates).

When a person is putting on weight this is because they are taking in more energy than they are using up. Obviously just keeping our bodies going uses up energy, and the amount of energy we need for this basal body function can vary according to a number of factors like body composition, age and stage of life, and other factors, possibly including the influence of drugs like antipsychotic medication. But even if there are differences in “metabolism” between people (and most experts think that these differences are likely to be much smaller than many people think), there is still scope to do something about the energy in/energy out equation. It is the voluntary activity part of activity that we can do something about – ie how much we move around. Or we can limit the amount of energy we take in by eating less, or eating less energy-dense food.

On the issue of genetic determination of weight, there is a lot of evidence that a tendency to be overweight or even obese, and a tendency to be thin, runs in families. But this doesn’t mean that there is nothing we can do about weight gain, because part of what is inherited is the tendency towards certain types of behaviour. The tendency to find the sensation of hunger particularly acute and tendency not to know when you are feeling full (or not to stop eating when you are feeling full) may be inherited. Similarly, there is some evidence that the tendency to be active is genetically determined – not only on the level of playing sport or not, but also for more mundane everyday activity, like fidgeting, getting up and walking about, wanting to move around etc. So, it may be harder for some people to control their weight than others, and some people might need to be more mindful of the “energy in/energy out” equation than others, but the same basic principles apply to everyone.

Another important aspect of beliefs about weight gain is a set of beliefs about the consequences of weight gain. It might be important to explore a number of different sorts of consequences – e.g. health consequences, social consequences, consequences for role, work or leisure activities.
Examples of the sorts of beliefs which people might hold could include:

- I see a lot of people who are fatter than I am, so it must be all right;
- I don’t know anyone who has died of being overweight, so I don’t believe that stuff about obesity causing cancer;
- My risk of developing diabetes or heart disease is lower than most people’s because (there is none in my family/ I used to play football/ I eat a lot of vegetables)
- Being overweight doesn’t stop me doing anything around the house
- It doesn’t matter if I am fat because I walk the kids to school and back every day
- I don’t feel any different at 13 stone than I did at 10.

Once again, we can’t pretend to know everything about the consequences of being overweight. Health promotion advice might include statements like “a third of cancers are caused by obesity” and “most heart disease could be avoided if people had a better diet” but these general statements actually summarise a whole mass of research and evidence, some of it contradictory, some of it flawed. On the other hand, we can be very confident that the general advice to keep weight within the BMI of 20-24 range is good advice, and that achieving this would certainly help a lot of people to lead healthier, longer and more fulfilling lives.

In the general population, being overweight is correlated with being unfit. It is difficult for overweight people to get fit for a whole range of reasons, but any increase in fitness will benefit an overweight person. Preferably, this increase in fitness will be accompanied by a loss of weight, but an increase in fitness without weight loss is definitely better than nothing.

Beliefs in this category will need to be discussed very sensitively. In our society there is a stigma attached to being overweight, with many members of the public erroneously believing that people who are overweight are morally defective, lazy or stupid. In fact, being overweight is a condition that invokes a huge amount of judgement and prejudice. Most of us can’t help but be touched by these prejudices, and there is evidence that being overweight can have a tangible effect on people’s lives – e.g. overweight people do less well when being interviewed for jobs.
A third important category of beliefs is beliefs about controllability of weight gain. Clearly, these beliefs are closely related to beliefs about the causes of weight gain – for example, if a person believes that she has put on weight because she has eaten too much carbohydrate rich food, she is likely to attempt to control future weight gain by trying to cut down on carbohydrates. Or in another example, if a person believes that her metabolism is responsible for her being overweight, she might not believe that there is anything she can do about it.

So beliefs about the causes of weight gain and its potential controllability are generally related in a coherent model of the problem (weight gain). It probably therefore makes sense to refer back to people’s causal beliefs when discussing the controllability of weight gain.

But other, more individual, factors are important too. A person may believe that the best way for him to control his weight would be to do more strenuous exercise, but may not believe that he it is within his power to do that exercise. He may lack confidence in his ability to carry out exercise behaviour (have low self-efficacy) or he may perceive numerous barriers to carrying out exercise (no suitable trainers, no-one to do it with, can’t afford gym fees etc.).

A person’s beliefs about the controllability of weight gain (or weight in general) are therefore determined not only what she believes about how bodies regulate their weight, but also what she believes about how well she can regulate her behaviour. The beliefs about weight gain/control provide the motivation and the intention to behave differently, but beliefs about self-control will determine (in part) whether the intended behaviour is carried out or not. Beliefs about self-control might be described in terms of habits, will-power, resisting temptation, etc. It is because it is not always easy to translate good intentions into good behaviour that we encourage people to develop specific action plans. Hopefully you can now see how these action plans need to incorporate behaviours that match up with the person’s beliefs, but the action plans also need to specify what the person will do when he or she encounters barriers, problems, temptations etc.

Finally, we need to look at a category of responses to weight gain called “emotional representations” in the literature. This is a rather complex construct, encompassing not only people’s emotional reactions to being overweight but their beliefs about those emotions. However, for our purposes,
what we need to do is to gauge how the service user feels about his weight. For example, does he feel angry that he’s gained weight, does he feel sad at the loss of the body he used to have, is he worried about the possible future consequences, or is he afraid of losing the approval of his family?

According to the self-regulatory model, when people are faced with a health threat (like the threat of weight gain) they do two things – they try to deal with the threat in more or less adaptive ways (as we have been discussing above), and they try to deal with the emotions engendered by the threat. So a person who has put on weight and feels really worried about it might do things to try to reduce the worry. They might talk to friends to seek reassurance, they might distract themselves by playing the Play Station, they might try to tell themselves that they don’t care. These are all strategies that people use to make themselves feel better, but they don’t necessarily tackle the problem itself. Problem-focused strategies (such as all the different strategies that people could use to try to lose weight) may have the additional effect of making people feel better about the problem, partly because they feel that they are addressing the problem, and partly because the problem-solving approach may actually have emotion-regulation benefits (e.g. doing more exercise can improve mood).

On the next few pages are three case studies which you can use as stimulus material for role plays or personal exercises on the use of beliefs about weight gain. The case studies give you a place to start, but to use them, you will need to think about the possible beliefs that each of these three individuals may have.

When using the case studies, you might like to keep in mind the following points:

People’s beliefs about weight control and models of weight-related illnesses are derived from a number of sources of information.

- Has the person any direct evidence about weight control of their own to draw on? What has happened when they have tried to lose/increase weight before, and how has this impacted on their beliefs?
Are members of the family overweight/underweight? What are their eating/exercise habits?

What have healthcare professionals told the person about the effects of medication, about diet and exercise?

Is there any history of possibly weight related illness in the family or among friends (diabetes, heart disease)?

How does the person feel about his/her weight?

What barriers are there likely to be to changes in eating or activity?

In addition explore barriers and facilitators of healthy living (eg family, their own mental health in terms of mood, lack of sleep, working, isolation, lack of knowledge. Elicit cultural beliefs (a session on cultural sensitivity including a presentation and information will be given during the 3 training days) and the role of their family/friends in maintaining life style. Three case studies which will be used in the training can be found at the end of this manual.

Summary

Using the patient centred assessment summarise the information and seek feedback that the summary is correct. For example “John you have told me that you first became ill about 2 years ago, but have felt well for the past 12 months. You live with your family who are very supportive and work part-time in JJB sports. Prior to your illness you were played rugby regularly. You don’t play anymore and the reason you gave was that you felt your friends whom you played rugby with thought you were a ‘crackpot’ after you developed your illness. Although you wanted to continue to play you felt that your friends were talking about you and you stopped going and have not played since. You have told me that you put on a lot of weight, about 3 stones after starting medication and you think the weight gain is to do with both the medication and the lack of exercise. You would like to do something to help you lose weight but don’t want to play rugby again – you would like to swim but feel too self conscious about your weight to go. You eat a reasonable diet mainly because your Mum cooks for you but you recognise that you drink too much coke (about 3 cans a day). You have also told me that you were interested in being part of this study because you want to try to lose weight and lead a more healthy life……. Is this correct and I have I missed anything out.
Identify individualised goals

Work in partnership with the client to establish specific goals which they want to work on. Use the information that you have gathered to do this – for example “to summarise you have said that you want to lose some weight and would like to do more exercise but you have found it difficult to be consistent with this. You have said that you find it difficult to be with lots of people and want to do something on your own and that you have a friend who will help you- have I understood this correctly”. I am wondering if we can turn this into a few specific goals that we can work towards, are you happy to do this.

Explain what goals are and why we write them down. Emphasise the following about goals

1) only take 2- 3 goals at the most
2) They must be focussed on a change
3) They must be patient centred (ie developed by the client)
4) They must be specific
5) They must be stated positively
6) They must be realistic and feasible
7) They must be measurable
8) They must be behaviours that can be incorporated into a persons lifestyle

An example would be:
To go swimming twice a week with a friend
To eat a healthier diet by ensuring that I eat at least 5 portions of fruit and vegetables daily
To be able to reach a target weight of 10 stone in 3 months
To be able to plan a weekly menu to ensure I eat healthily
To walk to and from work 4 times a week

Use the scale below to write down the goals and rate them
My healthy living Goals

Today's date

Goal number 1

I can do this now (circle a number):

0 1 2 3 4 5 6
Not at all Occasionally Often Anytime

Goal number 2

I can do this now (circle a number):

0 1 2 3 4 5 6
Not at all Occasionally Often Anytime
Below is an example of a sheet which you may want to print out for the client to read prior to setting goals.

**What are your goals?** We have provided some sheets for you to write them down. Your worker will help you with this if you want. Working with too many goals can be confusing. We would advise you to work with between one and three goals. Here is some advice for setting your goals:

- Ask yourself what you want to be able to do
- Be as specific as you can by stating how often you want to do something
- Set realistic goals, things you want to do in the future or used to do in the past
- State goals positively, start with ‘to be able …’ rather than ‘to stop ……’
  - e.g. ‘to be able to eat 5 portions of fruit and veg daily’ stay awake in the day’ rather than ‘to stop eating junk food every day’

Goals are things to aim for. Pick things that will help you to achieve a healthier lifestyle. So that you know how you are doing, we have written down a simple scale underneath each goal. Circle one of the numbers for each one. This will tell you how difficult you find each goal.

At the moment, you should choose goals that you want to aim for. As you do work with this programme the goals will become easier to achieve. Re-rating them every now and then using the same scale is an excellent way to monitor your own personal progress. Aim to do this at least monthly with your worker.

<table>
<thead>
<tr>
<th>Goal number 3</th>
<th>..........................................................................................................................</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>..........................................................................................................................</td>
</tr>
<tr>
<td></td>
<td>..........................................................................................................................</td>
</tr>
<tr>
<td>I can do this now (circle a number):</td>
<td>0</td>
</tr>
<tr>
<td>Not at all</td>
<td>Occasionally</td>
</tr>
</tbody>
</table>
Introducing the book

The healthy living book should be introduced to all participants. Introduce it as a book with lots of information on healthy living which they may find useful, eg local gyms and fitness/exercise classes, governmental guidelines for diet and exercise, information on how to eat more healthily, shopping and cooking healthily on a budget and a range of healthy recipes. Explain that the book is available in Urdu as well for participants and their families. For example “The book is something we have written to help you to make improvements to your life style including government recommendations for healthy living, exercises, healthy eating recipes, and written exercises that you can do to help you put your plans into action). You can take it away with you today and have a look through and we will work through some sections of the book over the next few sessions”.

Ensure that you check literacy levels in a non stigmatising way, for example “is there anything that would prevent you from looking at the book, ie visual, hearing, literacy or concentration difficulties. If there are difficulties then I would be happy to go through the book with you or I could audio tape sections if you would like me to.

Ensure that you ask if you think a friend or family may find a copy of the book useful.

Ending

Recap the session, decide next steps which might include asking a family member/friend to attend the next session, to have a read of sections of the book and see what they think, or it might be working on their goals if you have been unable to complete them in the session. Ask for feedback from the session and ask if they have any final questions. Arrange next appointment.
Session 2

Session 2 overview:

Review

Review goals

Develop a feasible and acceptable action plan (identifying barriers and facilitators to implementation)

Collaboratively plan intervention and next steps of the intervention

Ending: Feedback on session – final questions – next appointment

Review

Welcome patient, orientate to purpose and duration of session (30-40 minutes). Review, summarise (and re state the goals that were established) and seek feedback from session 1 – ie what they liked about the session what they would have liked differently. Ask if they have read any parts of the book and what they thought of it. Ask if there is anything that they want you to go through again. Ask participant if there are any issues regarding healthy living which they want to address in the session. Clearly state that the purpose of this session is to look at ways of translating goals into reality by devising an action plan to help look at the steps that are needed to move from a goal statement to enacting this.

Identify action plan for implementation

This is a key element of the intervention and must be emphasised. This is the transition phase from putting participant’s clear goals into practice. Firstly it is
important to establish with the participant how these goals will be implemented ie – an introduction to this could be something like the following

“Thank you for all the information that you have given me so far and I think you have done an excellent job in terms of identifying clear goals with which you want to work with. What I want to do is to support and help you in achieving these goals, and what would be useful at this point is to look carefully how we can achieve and implement these goals. It is also useful to think even at this early stage how we can incorporate these changes to become part of your regular routine. Can we first look at the steps that both you and I need to do to implement your goals?”

Using the participants goal (eg “you have stated that you want to go swimming at least 3 time a week, lets look at how this can happen” Then ask a series of related questions such as who do you want to go with (alone, friend/family), if wants to go accompanied how is this going to happen (ie has the friend or relative been asked, do they want you as the STR worker to accompany them the first couple of times) is there a swimming baths which is accessible, how much is it and is it affordable, is there any mileage in looking at discounts, 3 times may be a lot to start off with so breaking this down may be important in starting of with once a week and building up, identify with the participant which days they want to go, when and with whom and for how long). It is also important to ask if there are any other barriers or facilitators (ie things that will help and things that would stop them) to implementing their action plan- key issues may be motivation or if and when their mental health problems are worse- this might be simple actions for example you saying that you will give the participant a ring on the days that they going swimming for the first couple of weeks or writing out a timetable with them, or talking to a family member or friend. If there are major barriers, then plans should be made for overcoming them e.g. If I have difficulty getting out of bed in time to go swimming before work, I will…etc

With the participant write out the actions that need to be completed between the first few sessions similar to the example below. It should be emphasised that writing things down as in the action plan are important as we know (as with all of us) that if we write something down it is more likely to be achieved than if we hadn’t. The action plan should be seen as a working document and participants should be encouraged to bring it with them to every session and you should keep a photocopy for your own records and to remind you of any actions you need to do.
My Action Plan

<table>
<thead>
<tr>
<th>Action</th>
<th>Actions and by whom</th>
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</thead>
<tbody>
<tr>
<td>To go swimming 3 times per week</td>
<td>Identify the cost and distance of the local swimming pool (STR worker will do on Monday as well as seeing if there are any discounts that I am entitled to and tell me at my next session) (STR worker)</td>
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<tr>
<td></td>
<td>Ask my friend (Tom) if he will come with me on a regular basis ) I will ring him tonight (Me)</td>
</tr>
<tr>
<td></td>
<td>I don’t have any swimming trunks that fit me (I am fairly sure that my mum will buy me them but I need to check) (Me)</td>
</tr>
<tr>
<td></td>
<td>My best time to go swimming is around lunchtime (before I go to work) STR worker to find out specific opening times of the pool to make sure it fits in with work (STR worker)</td>
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</tbody>
</table>

Offer the option of the schedule groups

Ensure you offer the participant to attend the scheduled groups. The groups are completely optional and they are simply a method to help participants implement healthy living changes. The groups may or may not fit into the individual’s action plans but all participants must be given the option. If the groups are to be part of the participant’s healthy living intervention then they should be included in the action plans.

Ending

Recap the session, and reiterate next steps of the action plan i.e. who is doing what actions. Ask for feedback from the session and ask if they have any final questions. Arrange next appointment.
Session (3 - 5) Implementation of the action plan

<table>
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<th>Session 3 – 5 overview:</th>
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<tbody>
<tr>
<td>Review</td>
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<tr>
<td>Review progress on action plan and implementation steps</td>
</tr>
<tr>
<td>Collaboratively plan next steps for implementation and implement action plan</td>
</tr>
<tr>
<td>Monitoring progress</td>
</tr>
<tr>
<td>Ending: Feedback on session – final questions – next appointment</td>
</tr>
</tbody>
</table>

**Review**

Welcome participant, orientate to purpose and duration of session (30-40 minutes). Review, summarise (and re state the goals that were established) and seek feedback from session 2– ie what they liked about the session what they would have liked differently. Ask if they have read any parts of the book and what they thought of it. Ask if there is anything that they want you to go through again. Ask participant if there are any issues regarding healthy living which they want to address in the session.

**Review Progress on action plan and next implementation steps**

Review what actions have been completed and which ones have not – use problem solving strategies to resolve barriers to implementation. The main purpose of these sessions is to actually implement the action plan into routine life. There is a large amount of flexibility within these sessions to meet
individuals’ needs. To implement the plan may require a number of options and it is for you and the participant to collaboratively decide how to do this and make best use of the time that you have. For example it may be necessary or helpful to attend a swimming, exercise session with the participant, or to accompany them to one of the scheduled groups you are running. Alternatively it might involve a session with a family member in a session of changing or modifying the family diet - or it might be doing a live shopping and cooking session on an individual basis.

Ending

Recap the session, next steps of the intervention, ask them to read or listen to the intervention selected and reiterate what they have agreed to do before the next session. Ask for feedback from the session and ask if they have any final question. Arrange next appointment.
Session 6 & 7

Session 6-7 overview:

Review

Review progress (measure progress towards goals)

Review action plan

Ending: Feedback on session – final questions – closure of the session – next steps

Review

Welcome participant, orientate to purpose and duration of session (30-40 minutes). Complete a general review on wellbeing over the past few months. Ask participant if there are any issues regarding healthy living which they want to address in the session.

Review Progress on Intervention

Review and rate progress on achievement of goals and if lifestyle changes have been incorporated into the participant’s routine life. With the use of the action plan and participant information collaboratively identify what further steps need to be taken to achieve original goals. Collaboratively problem solve ‘stuck points’ and barriers. Actively seek participant feedback on other benefits or limitations resulting from the healthy living programme. Re-rate original goals.
Review action plan

Review action plan – have a focussed discussion on any changes or amendments to the action plan which the participant wants to make. For example their changes in the participants life, work or leisure may mean that part of the plan is difficult.

Ending

Recap the session, next steps of the intervention, ask them to read or listen to the intervention selected and reiterate what they have agreed to do before the next session. Ask for feedback from the session and ask if they have any final questions. Arrange next appointment.
Session 8 (months 10-12)

Session 10

Review

Review goals

Review progress and plan next steps

Plan next steps

Ending: Feedback on intervention

Review

Welcome participant, orientate to purpose and duration of session (30-40 minutes). Review, summarise (and re state the goals that were established) and seek feedback from session 2—ie what they liked about the session what they would have liked differently. Ask if they have read any parts of the book and what they thought of it. Ask if there is anything that they want you to go through again. Ask participant if there are any issues regarding healthy living which they want to address in the session.

Review and rate goals

Re rate original goals and review progress.
Review progress

Have a focussed discussion on further plans, for example if the participant has incorporated change into life style- explore how this can be maintained, and identify barriers and facilitators to maintenance and strategies that the participant can put into place to help maintenance. If not incorporated into life, or there have been changes which have prevented changes into their life style collaboratively problem solve.

Feedback

Discus with the participant their views of the healthy living intervention- explore timing, duration of sessions, what was helpful, what was not helpful, what changes could be made to the intervention, explore views on the book, optional groups if they used them.

Ending

Recap the session, next steps of the intervention, ask them to read or listen to the intervention selected and reiterate what they have agreed to do before the next session. Ask for feedback from the session and ask if they have any final questions. Arrange next appointment.
Section 3 – Audio taping and supervision

**Audio taping**

You will be asked to audio tape all your sessions with participants – you will be supplied with audio equipment. Participants will be asked to consent to this by the researchers and if any patients refuse then the researchers will inform you. For participants that have consented please confirm their agreement at each session. Sometimes participants are reluctant to tell you information with the tape on – please ensure that you tell participants that it is confidential and that the purpose of the tapes is to listen to what the STR worker is doing rather than what the patient is saying. Ensure that the patient knows that if there is anything that they want to discuss with the tape off then they can do this. If there are sessions where you are accompanying a participant to an activity it is not necessary to tape the session.

**Supervision**

All workers delivering the intervention will receive supervision on a fortnightly basis – trial supervision does not preclude any other supervision sessions that you may have. Supervision will be on a fortnightly basis with Tim Bradshaw with input from Karina Lovell and Alison Wearden. Supervision will be conducted over the telephone or face to face dependent on your preference and availability.

Section 4 - Monitoring

You will be keeping your own notes for the clients you are seeing. We will ask you to keep a monitoring sheet for each patient (see patient contact sheet at the end of this manual) and the groups you run. This information is very important to us as it will tell us how many sessions patients attended, and what specific interventions they used. The participant contact sheet requires you to complete the participant study number (not the patient’s name), session number, session length and brief details of the content of the session. In the group participation sheet it would help us if you completed these on any group you ran, and include details of date, the number of participants you invited the number attended and brief details of the type of group (e.g. walking, demonstration etc).
Section 5 – Trial procedures

Audio taping of sessions

Patients sign a separate consent to the taping of sessions ie patients can opt for inclusion into the trial but can refuse consent for taping of sessions. If a patient refuses consent to taping therapists will be informed when allocated patients. For patients who have given signed consent - therapists should ask at every session that consent for taping remains. All audio tapes should be labelled with pt initials, pt ID number, date and session number. All audio tapes should be stored in a lockable cabinet and will be hand delivered to the trial team.

Patient notes

Patient notes should be kept in individual files labelled with patient name, patient ID and kept in a lockable cabinet. Therapists will keep a log of each patient session (in therapist manual) with date, time and details. Patient logs will be hand delivered to the trial team.

Supervision

Supervision will occur every 2 weeks on an individual basis with Tim. A supervision log will be kept by supervisors.
Section 5 - HELPER first interview guide for STR workers (Crib sheet)

Instructions about how to use the interview

This guide has been provided to assist STR workers to conduct the first health education session with participants in the HELPER InterACT study. The interview should be conducted in a relaxed and conversational manner in order to develop a good rapport with the patient. The questions can be followed flexibly and it is not essential to ask all questions if you think an answer has already been provided. In some instances it may seem appropriate to conduct the interview over the first two healthy living sessions. Whilst conducting the interview STR workers should remember the importance of listening attentively to what the person is saying and making brief summaries to ensure they have an accurate understanding of what the person has told them.

Introduction and orientattion, for example:

“my name is ............... and I am a Support Time Recovery Worker employed to help deliver the healthy living intervention being evaluated by the HELPER InterACT study. Thank you for agreeing to participate in the study and for seeing me today. The aim of today’s session is for us to get to know one another and for me to find out more about your current health and lifestyle. How does that sound to you? Is there anything specifically that you wanted to get from today’s session?

Lifestyle

“I’d like to start by asking you some questions about your lifestyle and how it has changed since you first started to receive treatment for your mental health problems?”

- So tell me if you think there have been any changes to your lifestyle since you first developed mental health problems?
• What sort of things do you think are important to maintaining a healthy lifestyle?

• What do you do at the moment to stay fit and healthy?

• Tell me about the types of things you eat in a typical day? (probe – how many portions of fruit and vegetables, how much fried food, sugary drinks, type of bread preferred etc.)

• Tell me about what types of physical activities you participate in? (for each activity probe – frequency, duration, intensity of activity etc.)

• Would you like to make any changes to your current lifestyle in order to make it healthier?

Eliciting beliefs about weight gain

“Now I would like to ask you some questions about your current weight and how you feel about it? How does that sound?”

• How would you describe your weight at the moment? (probe – do they consider themselves to be of normal weight, overweight or obese)

• Has your weight changed since you started treatment for your mental health problems? Probe – amount they think they gained or lost and timescale)

• What do you think are the reasons for your weight gain/loss? (probe – beliefs e.g. change in appetite etc. and source of information)

• What do you think are the consequences for you from gaining/losing weight? (probe – worries about health, appearance, functioning etc.)
• How much control do you feel that you have over weight? (probe – what sorts of things the person does to control their weight)

• Would you like to make any changes to your weight? (probe – if they want to loose weight how much?)

Summary

“Alright can I just check that I have understood what you have told me correctly (summarise key points about lifestyle issues and weight including beliefs about causation, control and desire to change) does that sound about right so far is there anything important that I have missed?”

Barriers and facilitators

“Now I would like to ask you about what factors you think will help you to make changes to your lifestyle and/or loose weight and also about what factors you think might make this difficult to achieve”

“Okay so you have told me that the things you would most like to achieve is/are (list what they want to change below):

1. __________________________________________________________

2. __________________________________________________________

3. __________________________________________________________
“What factors do you think will help you to make this/ these changes?
(record all ideas expressed and use prompts below when necessary)

Prompts

- access to exercise facilities
- encouragement from family member / friend
- Having a clear plan
- Sharing goals with others

“Now tell me what factors might make it difficult for you to change your lifestyle and/or loose weight or might get in the way of success”? (again list all suggestions made but use prompts below when appropriate)

Prompts

- low energy
- poor motivation
- lack of resources
- lack of support
- poor self confidence

Collaboratively agree goals (using goal sheets)

Ending
Section 6 – Case studies

Case study 1

Yasser aged 22

Yasser lives at home with his parents and 16 year old sister. Two brothers (one older, one younger than Yasser) live away from home. Since leaving school, Yasser has worked in the restaurant trade, mainly as a waiter in local restaurants, although he has also done kitchen work. He first started to be ill about two years ago, and has not now worked for twenty months, although he is hoping to return to part-time work soon. Yasser had been engaged to get married, but when he became ill, the engagement was called off and he rarely sees his ex-girl friend.

Although he is rather shy, Yasser has always been quite active, playing cricket and football at school and he has played with various parks football teams over recent years. He stopped playing when he became ill, and would like to start up again, but has lost touch with a lot of the friends he used to play with. Yasser is six foot tall, a good-looking boy, and has never had any problems with his weight, but since starting to take Olanzapine, he has gained 6 kg (almost 1 stone), which upsets him. Yasser’s parents both suffer from Type 2 diabetes for which they take tablets. They have also received advice on diet and exercise, and have recently got into the habit of taking a half hour brisk walk at 6.30 each morning. Yasser has thought about going out with them, but has not yet managed to get up in time.

Yasser’s mother prepares the food in his house, and the diet predominantly reflects her origins in Pakistan, with lots of home-made vegetable and daal
curry dishes, chapattis and yoghurt, but Yasser and his sister also enjoy meals like egg, chips and baked beans, and shepherds pie with peas, washed down with diet coke. No-one in the family eats any pork products, and Yasser’s parents eat a predominantly vegetarian diet.
Case study 2

Christopher aged 21

Chris was half way through a degree in politics when he suddenly became acutely ill and was hospitalised. On his discharge from hospital, he left his course in Nottingham to return to live with his mother in East Lancs, but the arrangement broke down when his mum became depressed and could no longer cope with Chris’s changed behaviour (particularly his excessive sleeping and his smoking). After an unsettled spell of living with various friends, and with his grandma, Chris was found a place in supported accommodation, where he now lives with two other young men recovering from mental health problems. He is not currently working, but is doing an online Spanish language course, and plans to go back to university one day.

Chris was always a very skinny young man, in spite of the fact that he ate whatever he wanted and drank whatever he wanted too, including a large amount of strong bottled beer. The most exercise he ever got was playing his drums in a band which he set up with several friends from school. During his teenage years, Chris’s Mum despised of his diet which seemed to her to consist of sausages, bagels, orange juice and beer, with very little variety. Chris’s Mum, a social worker, lives on her own now (his Dad remarried and moved down South many years ago). She is a bit of a fitness freak, goes running, biking and walking, and she eats a pretty healthy, mainly vegetarian diet. She too has always been thin, although she has put on a little weight recently, which annoys her. Chris sees his Mum several times a week and they are getting on much better now that they don’t live together.

Chris was prescribed olanzapine while he was in hospital, and is still taking it. He has been having regular health checks, and although he has put on some...
weight (about 3kg) he is happy with this, as he thinks he was too thin before, and he is still pretty thin. He doesn’t think he could ever get fat because he’s just not that body type. Chris’s doctor has told him that he needs to do some exercise, but Chris hasn’t done anything about this. Chris is aware that both of his uncles (his Dad’s brothers) have had heart attacks, but as he never sees them, he never thinks about this.
Case study 3

Sarah aged 26

Sarah is 26. She lives on her own in a council flat. Her six year old daughter, Hayley, is currently living with her Mum. Sarah is on good terms with her Mum and sees her regularly. She takes Hayley to school a couple of days a week and sees her most evenings. Sarah was working in a factory before she became ill, but has been unable to get a job recently, and is currently unemployed. She spends her day watching daytime TV, doing her shopping and housework, and doing word puzzles.

Sarah was overweight as a teenager and has gained even more weight since becoming ill two years ago. Her BMI is now getting seriously high, at 31.5. Sarah’s Mum and her older sister, are also quite overweight, and the teachers at Hayley’s school are now starting to say that Hayley is overweight too. This really upsets Sarah. In fact Sarah feels pretty fed up about her weight. Hardly any of her clothes fit her, and she is embarrassed when she has to sit next to someone on the bus, because she seems to take up most of the space.

Sarah has been on more diets than she can count, but never seems to be able to stick to them for more than about a week. She has been advised to take up exercise, and wants to do some, but the only exercise she likes is swimming and the nearest swimming pool is a mile and a half away. She can’t afford the bus fares to go regularly, and secretly is too ashamed to put on a swimming costume anyway (and she hasn’t got one that fits). Sarah’s friend, who is much thinner, said she would go jogging in the park with her, but Sarah thinks that they would look like Laurel and Hardy, and is just too embarrassed to go.
Sarah isn’t even hungry a lot of the time, but she eats because she is bored or upset. She doesn’t really have any regular mealtimes. Her favourite food is pizza, and she has been known to eat a whole packet of biscuits in one sitting. Sarah doesn’t really drink alcohol, except maybe at Christmas, but she smokes 30 a day. Whenever she tries to stop smoking, she puts on even more weight. Since being on her medication, Sarah has gained 4kg, and she now has pains in her hips, which means that she walks with a bit of a limp.
HELPER first interview guide for STR workers

Instructions about how to use the interview

This guide has been provided to assist STR workers to conduct the first health education session with participants in the HELPER InterACT study. The interview should be conducted in a relaxed and conversational manner in order to develop a good rapport with the patient. The questions can be followed flexibly and it is not essential to ask all questions if you think an answer has already been provided. In some instances it may seem appropriate to conduct the interview over the first two healthy living sessions. Whilst conducting the interview STR workers should remember the importance of listening attentively to what the person is saying and making brief summaries to ensure they have an accurate understanding of what the person has told them.

Introduction and orientation, for example:

“my name is .................. and I am a Support Time Recovery Worker employed to help deliver the healthy living intervention being evaluated by the HELPER InterACT study. Thank you for agreeing to participate in the study and for seeing me today. The aim of today’s session is for us to get to know one another and for me to find out more about your current health and lifestyle. How does that sound to you? Is there anything specifically that you wanted to get from today’s session?”

Lifestyle

“I'd like to start by asking you some questions about your lifestyle and how it has changed since you first started to receive treatment for your mental health problems?”
So tell me if you think there have been any changes to your lifestyle since you first developed mental health problems?

What sort of things do you think are important to maintaining a healthy lifestyle?

What do you do at the moment to stay fit and healthy?

Tell me about the types of things you eat in a typical day? (probe – how many portions of fruit and vegetables, how much fried food, sugary drinks, type of bread preferred etc.)

Tell me about what types of physical activities you participate in? (for each activity probe – frequency, duration, intensity of activity etc.)

Would you like to make any changes to your current lifestyle in order to make it healthier?

Eliciting beliefs about weight gain

“Now I would like to ask you some questions about your current weight and how you feel about it? How does that sound?”

How would you describe your weight at the moment? (probe – do they consider themselves to be of normal weight, overweight or obese)

Has your weight changed since you started treatment for your mental health problems? Probe – amount they think they gained or lost and timescale)

What do you think are the reasons for your weight gain/loss? (probe – beliefs e.g. change in appetite etc. and source of information)
What do you think are the consequences for you from gaining/losing weight? (probe – worries about health, appearance, functioning etc.)

How much control do you feel that you have over weight? (probe – what sorts of things the person does to control their weight)

Would you like to make any changes to your weight? (probe – if they want to loose weight how much?)

Summary

“Alright can I just check that I have understood what you have told me correctly (summarise key points about lifestyle issues and weight including beliefs about causation, control and desire to change) does that sound about right so far is there anything important that I have missed?”

Barriers and facilitators

“Now I would like to ask you about what factors you think will help you to make changes to your lifestyle and/or loose weight and also about what factors you think might make this difficult to achieve”

“Okay so you have told me that the things you would most like to achieve is/are (list what they want to change below):

1. _______________________________________________________

2. _______________________________________________________

3. _______________________________________________________


“What factors do you think will help you to make this/these changes? (record all ideas expressed and use prompts below when necessary)

Prompts

- access to exercise facilities
- encouragement from family member / friend
- Having a clear plan
- Sharing goals with others

“Now tell me what factors might make it difficult for you to change your lifestyle and/or loose weight or might get in the way of success”? (again list all suggestions made but use prompts below when appropriate)

Prompts

- low energy
- poor motivation
- lack of resources
- lack of support
- poor self confidence
<table>
<thead>
<tr>
<th>Date</th>
<th>Session Number</th>
<th>Duration of session (minutes)</th>
<th>Brief details of the session – ie goal setting, action planning, meeting family/friends, accompanied session to group or activity</th>
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Appendix 5  The InterACT trial acceptability interview topic guide

Interview schedule, version 1 (14 February 2012)

Introduction
- Explanation of ethics, consent and confidentiality of interview and analysis.
- Explanation of objective of acceptability substudy.
- Structure and duration of the interview.
- Any questions?

Clarify – talking about intervention rather than the research.

Context
- Tell me about the healthy living intervention?
- Can you tell me about your experiences while taking part in the healthy living intervention?
  Probe – Individual and groups or individual only? If individual only why not groups?

Process
- What were your initial expectations of the healthy living intervention?
- What were the specific advantages and disadvantages of the healthy living intervention?
  Probe
  - Time commitments, timing of appointments, travel, etc.
  - (What specific thing achieved change?)
- What specifically did you like/dislike about the healthy living programme?
  Probe
  - What did you think about the goal-setting and action plans?
  - How realistic were the goals you set?
  - How well did you feel you achieved your goals.
  - If you did the programme again, would you do anything differently?
  - (What specific element/thing achieved change?)
- Were you provided with information about the website?
  Probe
  - Did you use it? If not, why not?
  - How many times did you go on to it?
  - Did you find it useful?
  - How did you find getting access to the internet?
  - Did it help with the intervention?
Were you provided with information about a booklet to help with the intervention?  
Probe
- Did you use it?
- How many times did refer to it?
- Did you find it useful?
- Did it help you achieve your goals?

Which would/did you prefer, the booklet or the website? Why?

STR worker – how did you get on with your STR worker? Good points? Things that could be improved?  
Probe specific intervention factors (i.e. goal-setting, action plans, implementation of action plan, interventions and non-specific factors such as warmth, empathy, listening)
- Some people have said that it was useful for them that their STR worker knew about their past – what you think about this? Did you find this useful? Why?
- Some people have said that they found it useful that their STR worker knew about their mental health whereas others did not – how do you feel about this?

What was your experience of your family/carer being involved in your treatment?  
Probe
- Were family involved? If so, what were the advantages and disadvantages of your family being involved? How helpful was it?

Did the STR worker offer to see your family or other people involved in your care, for example close friends? If so, what was the outcome? How did you feel about them being involved?

Outcome

Do you feel that you have benefited from being on the programme?  
Probe
- Any specific benefits for healthy living or other benefits for functioning (social, occupational/school, private, leisure, family relationships), mood/depression, anxiety, stress, the way you feel about yourself, your appearance?
- (What specific thing achieved change?)

Would you recommend this programme to other people with similar problems to your own?  
Probe
- Yes/no answers on reasons for their response.
- (What specific thing would you recommend to someone about the programme or is it the programme as a whole?)

Is there anything that you would add to or change about the intervention?  
Probe
- For example, some people have said that a weekly weigh-in would be useful whereas others have said that they would not find this useful? What do you think?

Is there anything else that you would like to say about the healthy living intervention?
Ending

- Thank participant for their time and information.
- Next steps: would they like a copy of the transcript to be sent to them for validity checking?
- A one-page copy of results will be sent to all participants.
I’d like to talk to you today about your drug use and what you think about drugs. I am interested in hearing all about your experiences and ideas.

I should remind you that everything you tell me will stay confidential unless I have serious concerns about your or other people’s welfare. What are your thoughts about this?

1. How do you feel about being here today? Any questions before we begin?
2. How are things going for you at the moment in general?

I thought it might be easier for me to draw a timeline of when you have used drugs in the past up to now. This is so I can get a better idea of what was going on for you at those times. I’ve got a few questions here that it would also be good to talk through.

[Fill in timeline for drug use]

3. I’d be interested to know about how your drug use has changed over the past months/years. Is that okay? In what ways has your drug use changed?
   - Reflect on pattern.
   - First occasion of use.
   - Current use.
   - Peaks/dips.
   - Related events/context.
   - Good things/bad things.
   - Thoughts, feelings, beliefs, social environment.
   - Triggers to think about giving up.

4. You’ve probably picked up lots of messages from your friends, family and doctors about drugs. What kind of messages have you heard?
   - Opinions about the messages.
   - Feelings about messages.
   - Spiritual/faith healers.
   - Opinions about other people’s use.
   - Different substances, situations, reasons for use, ways of voicing opinions.

5. What do you see for yourself in the future?
   - How would you like things to be different?
   - Drug use.
   - Reasons.
   - Timescale.
   - Possible influences.
6. (If not yet mentioned) People have lots of opinions about whether drugs and mental health are connected. Have you got any opinions about that?
7. I think we’ve covered most of what I planned. Is there anything else that you’d like to talk about?
8. How did you find it going through all this?

*Reflections, affirmations, summaries, open questions*
Appendix 7  The Rethinking Choices After Psychosis (ReCAP) trial psychoeducational materials

Facts about cannabis

1. Like most other psychoactive substances which produce euphoric effects, the regular, heavy use of cannabis may result in a cannabis dependence syndrome. There is now a growing body of evidence that suggests there is a cannabis dependence syndrome which is consistent with that of other classic drugs of dependence.

2. There is now evidence that cannabis also produces that other major characteristic of drug dependence, a withdrawal syndrome.

3. THC is to cannabis as nicotine is to tobacco. Different plants and plant strains of varying quality may yield differing quantities of THC. THC, like nicotine, is the substance primarily responsible for the development of cannabis dependence.

4. Approximately 10% of those who ever use cannabis become daily users, and approximately 20-30% use cannabis on a weekly basis.

5. The main health problems arising from long term cannabis abuse are related to the respiratory system. Like tobacco, the inhaled smoke from burnt plant material contains tar, carbon monoxide and carcinogenic substances. These have contributed to cancers of the upper airways and oral cavity, as well as diseases such as emphysema and increased risk of bronchitis and pneumonia.

6. Women who smoke cannabis are exposed to the risk of reduced fertility, low birth weight babies and possible contribution to birth defects.

7. A number of potentially harmful psychological effects are associated with long term cannabis abuse. These include:
   - Changes in short term memory and difficulty concentrating.
   - Some individuals appear to be at risk of development of symptoms of psychosis.
   - Some individuals appear to experience reductions in motivation and achievement of goal-oriented tasks, including school and work performance.

8. Restricting smoking to weekends or social occasions is often difficult to achieve in the long term.
How does your cannabis compare?

1. How much cannabis do you smoke each week/month? (It may be helpful to fill out the weekly use form)

2. How much do you pay for your cannabis each week? (It may be helpful to fill out the weekly use form)

3. Compared to other people you know that smoke cannabis - is the amount that you smoke:
   - (a) less than people you know?
   - (b) about the same as other people you know?
   - (c) more than other people you know?

4. What would you consider to be:
   - an average daily amount of cannabis use?
   - an average weekly amount of cannabis use?
   - an average monthly amount of cannabis use?

5. In the UK how much do you think the heaviest 5% of cannabis users smoke in a typical week/month?

6. In the UK how much do you think the heaviest 10% of cannabis users smoke in a typical week/month?
Managing withdrawal symptoms

People who have been using cannabis heavily over a period of time sometimes experience some withdrawal symptoms when they stop. Withdrawal is typically relatively mild and short-term.

The most common symptoms are:
- Irritability
- Urges to smoke – cravings
- Anxiety
- Depression
- Anger
- Confusion

The physical symptoms may include:
- Sleep problems
- Restlessness
- Loss of appetite
- Tremors
- Night sweats
- Diarrhoea

Even though these symptoms may be uncomfortable they are not dangerous and will pass.

Withdrawal symptoms can be seen as positive signs. They actually show that the body is recovering and re-adapting to being no longer dependent on cannabis. They are short term and it is impossible for them to persist for a great length of time – most will gradually resolve within 7-10 days.
Appendix 8  Example image from the Rethinking Choices After Psychosis (ReCAP) trial DVD
Appendix 9 The IMproving PArticipation in Cognitive Therapy (IMPACT) trial protocol

A randomised, controlled trial of cognitive remediation

Introduction
Cognitive Remediation (CR) is a method for improving neuropsychological function in schizophrenia. In essence the intervention is a form of ‘brain training’, consisting of regular practice on a number of mental puzzles. In clinical trials, CR has been shown to improve:

i. executive function (Kurtz et al., 2001, 2004; Penades et al., 2006; Reeder et al., 2004; Twamley et al., 2003; Wykes et al., 1999, 2007);
ii. attention (e.g. Kurtz et al., 2001, 2004; Medalia et al., 1998; Silverstein et al., 2005, 2007; Twamley et al., 2003);
iii. long term memory (Kurtz et al., 2001, 2004; Penades et al., 2006; Twamley et al., 2003; Wykes et al., 1999);
iv. insight into cognitive problems (Granholm et al., 2005); and
v. positive symptoms (Reeder et al., 2004).

Whilst previous meta-analyses have reached conflicting conclusions about the effect size of the intervention (Pilling et al., 2002), more recent trials have produced increasingly positive results, as the intervention and its associated outcome measures have become more sophisticated and specific. Furthermore, there is evidence for combining CR with other interventions in trials of rehabilitation for the severe and long term mental illness (Bell et al., 2007; Mueser & McGurk, 2007; Silverstein et al., 2005, 2007).

We hypothesise that CR will enhance the efficacy of the cognitive behavioural therapy (CBT) by improving cognitive functioning, especially attention and executive functions, (such as set shifting). If so, we expect that those who receive CR will received greater benefit from CBT, by virtue of being able to acquire more complex skills and reaching a better understanding of their problems. We therefore predict that they will score lower on the Psychotic SYmptom RATing Scales (PSYRATS; Haddock et al., 1999), which measures the psychotic symptoms targeted by CBT. We also predict they will get better more quickly and score more highly on a scale that describes the quality of engagement in CBT, designed by Professor Gillian Haddock (personal communication). The scale is already being used in an MRC-funded trial of cognitive behavioural therapy and motivational interviewing for drug misuse conducted at the University of Manchester. Other secondary measures will include: other symptoms; neuropsychological function; cognitive insight; attitudes to illness; vocational achievement; and self-concept.

Methods

Sample
64 patients on the waiting list for CBT delivered via Lancashire Care’s Early Intervention Service (EIS).

- **Inclusion criteria:** DSM 4 schizophreniform disorder, schizophrenia, schizoaffective disorder, delusional disorder or psychosis NOS; age 18-35; capacity to consent.
- **Exclusion criteria:** DSM 4 substance dependence; organic brain disease.
Procedure

Recruitment
Participants will be recruited via contact with NHS staff, who will first approach patients about assessment. Participants will be recruited from the existing waiting list or via the allocation procedures for the CBT service at the EIS. After identification they will be approached, informed about the trial – including being given a patient information sheet. Their capacity to consent will be assessed and they will be given 24 hours to decide whether to take part. Should they consent they will be asked to sign a consent form before their baseline clinical assessment (see: Assessments, below).

Allocation
After the baseline assessment participants will be allocated randomly by telephone contact with an independent administrator to receive CR or the active control treatment (see: Intervention, below).

Interventions

The CR Intervention
This is based on the commercially available CIRCUIITS package delivered via the internet or CD. This is in turn based on the intervention used in Wykes et al., (1999), used as the basis for Drake et al.’s (2007) CR trial which is used to power this trial.

Participants complete 40 hours of neuropsychological tasks in the form of increasingly complex puzzles (e.g. find a route around a map to a designated objective) or socially framed tasks (e.g. write applying to attend a given event, using a framework provided by the programme), all displayed using attractive, interactive graphics. These tasks are spread over the 12 weeks of the intervention, delivered at the subject’s own pace. This typically takes the form of 3–4 one hour sessions per week.

Participants will attend community services if they have no access to home computers. A therapist will assist the progress of those engaged in the intervention by helping them attend the community services, monitoring and recording all participants’ progress and supervising if necessary.

The Control Intervention
This (Befriending) will consist of time-matched, non-directive social contact from a Support, Training and Rehabilitation worker provided through the EIS service.

Standard Care
As part of standard care in the EIS both groups will receive input from a case manager and a psychiatrist, who will provide a standard package of psychosocial care and medication management. Thus the care participants receive from the EIS will not be fundamentally altered.

CBT
After CR or befriending participants will proceed to CBT, delivered as part of the Lancashire Care EIS. There is a waiting list for this treatment which currently exceeds the period required to administer cognitive rehabilitation. Thus neither control or intervention patients will be disadvantaged in terms of access to CBT by their participation in the trial. The therapists are suitably qualified in delivering specialist CBT for psychosis and exclusively employed to provide it. This service’s CBT consists of 12–30 weekly sessions of approximately one hour aiming to engage participants; improve their use of coping strategies for their symptoms; progress to investigating the schemata underlying them; and then develop an overall formulation, using a normalising rationale but incorporating relapse-prevention strategies.

CBT model fidelity will be rated on a randomly selected sub-sample using the CTS modified for psychosis (Devane et al., 1998).
Therapists will be asked to record the number and date of sessions and score overall progress during therapy on a suitably modified Haddock scale of CBT-complexity. After CBT the assessor will rate the participants’ scores from notes, to maximise reliability of this outcome.

Assessments

Baseline
Symptoms will be recorded with the PSYRATS (Haddock et al., 1999), Calgary Depression Scale for Schizophrenia (CDSS, Addington et al., 1996) and PANSS (Kay et al., 1987); this will take 35 minutes.

Cognitive insight will be rated using the Beck Cognitive Insight Scale (Beck et al. 2005), insight using the Birchwood Insight Scale (Birchwood et al., 1994) and self esteem using the Rosenberg Self Esteem Scale (Rosenberg, 1962). Beliefs about illness will be rated using a modified form of the Illness Perception Questionnaire (IPQ, Lobban et al., 2005). This will take about 15 minutes.

Overall illness severity and social dysfunction will be recorded with the Clinical Global Impression and Global Assessment of Functioning symptom and social functioning subscales (GAF-S & -F). This will take 1 minute.

At a second interview, neuropsychological function will be rated with measures of:

- executive function and metacognition (Metacognitive Wisconsin Card Sort Test, Koren et al., 2004);
- vigilance (Continuous Performance Test and Trailmaking A, Reitan & Reitan 1958);
- set alternation (Trailmaking B, Reitan & Reitan 1958);
- long term memory (the Logical Memory Test and Rey–Osterieth Complex Figure Test);
- IQ (Wechsler Test of Adult Reading and Wechsler Adult Intelligence Scale (revised) block design subscale).

This will take about 40 minutes.

After First Intervention
After the intervention (after 12 weeks) the same measures, apart from the WTAR & WAIS, will be re-rated by the assessor, from whom allocation group (CR or control) will be masked.

During and After CBT
During CBT the assessor will re-rate the PSYRATS every six weeks, up to thirty weeks. At thirty weeks they will also rate the same measures as for the second interviews. Working Alliance Inventory score (Couture et al., 2006) and Denver Recovery Markers Inventory (MHCD, 2006) will also be included.

Analysis
The main outcome will be the PSYRATS. Curves will be fitted to the longitudinal data using mixed effects models estimated by maximum likelihood methods. Allocation group (to CR or befriending) and potential confounders will be independent variables and the data will be clustered by cognitive–behavioural therapist.

The pattern of any missing data (e.g. due to drop-out) will be analysed using logistic regression to test whether the assumptions underlying this type of modelling (i.e. data ‘missing-at-random’) are met.

The principal secondary outcomes will be number of sessions and CBT complexity score. Others, adjusted for multiple testing, will include neuropsychological measures, global illness severity & dysfunction, attitudes to illness, cognitions and self esteem. In the event of positive results the effect of including process measures related to neuropsychological variables and attitudes will be examined.
**Power**

Based on a t-test of final interview scores, with an alpha value of 0.05 and power of 0.80, 64 participants allows detection of a difference between groups of effect size \( d \) of 0.50 (PS v 2.1.31, Dupont & Plummer 1997; using methodology from Dupont & Plummer 1990). This difference represents 8.1 points in PSYRATS totals (based on data from a first-episode sample in Lewis et al., 2002).

The same data-set shows that there is substantial independence between measurements made at successive points in follow-up six weeks or more apart. Thus one may make the approximation that data from the \( n = 6 \) follow-up interviews (at six week intervals; see Figure 1) will each contribute independently to estimating outcome, which in turn would reduce the standard deviation for the control mean across the repeated measures by \( 1/\sqrt{n} \). This approximation reduces the minimum detectable difference of approximately 3.4 points in PSYRATS total (about 25% of the controls’ overall mean score for the repeated measures).

Unpublished data from a recent trial in 67 schizophrenia-spectrum psychosis sufferers of cognitive remediation combined with social cognition training compared to control supportive therapy (Eack and colleagues, in press) found benefits of \( d \) 0.48 for a composite neuropsychological measure similar to the tasks proposed here and \( d \) 0.51 for symptoms.

**References**


Appendix 10 The InterACT trial protocol

1. Title

1.1 Programme title
The HELPER programme (HEalthy Living and Prevention of Early Relapse).

1.2 Stream title
Stream 3: A Healthy Living Intervention to encourage activity, improve diet, and control weight gain in people with a first episode of psychosis within the past three years.

1.3 Trial acronym
INTERACT Trial (INTERvention to encourage ACTivity, improve diet, and control weight gain).

2. Introduction

2.1 Background
The life expectancy of adults with schizophrenia is reduced by about 15 years when compared with the general population (Hennekens et al., 2005), and while some of this premature mortality is accounted for by suicide, approximately 62% of all deaths are attributable to natural causes (Harris & Barraclough, 1998). Adults with a diagnosis of psychosis are twice as likely as members of the general population to suffer from ischaemic heart disease, stroke, hypertension, epilepsy or diabetes by the age of 55 years (Hippisley-Cox & Pringle, 2005).

This poor physical health may be explained both by the side effects of antipsychotic medication (Marder et al., 2004) and by the unhealthy lifestyles that many individuals with psychosis lead (Brown, Inskip & Barraclough, 2000). People with psychosis have been shown to take less exercise (McCreadie, 2003), eat poorer diets (McCreadie et al., 1998) and to be significantly more likely to smoke (Brown et al., 1999) than members of the general population. They are more likely to be obese (Homel et al., 2002) and show a higher prevalence of metabolic syndrome (Sacks, 2004) and diabetes mellitus (Bushe & Holt, 2004). Patients taking second-generation antipsychotics, which are frequently prescribed to control symptoms of psychosis, are at particular risk of weight gain (Green et al., 2000). The risk of antipsychotic induced weight gain may be even higher among young people experiencing a first episode of psychosis (Zipursky et al., 2005). Recent guidance from the Department of Health (2006) has therefore highlighted the need to develop and evaluate health education programmes for people who have recently had a first episode of psychosis.

2.2 Development of the intervention
In deciding on the form of our intervention, which will be a pragmatic Phase II exploratory trial (Craig et al., 2008) we carried out four pieces of work (collectively termed Phase 1 work), and then synthesised the findings. Firstly, we reviewed studies already in the literature, focusing on controlled interventions. Secondly, we carried out two qualitative studies, one with service users and one with case managers, to discover their views on the content, format, setting and mode of delivery of the proposed intervention. Thirdly, we reviewed the key features of Leventhal’s self-regulatory model in order to provide a theoretical underpinning for our intervention. Finally, we considered how to make our intervention culturally sensitive for delivery in a multi-cultural environment.

A systematic review and meta-analysis of ten non-pharmacological interventions to manage antipsychotic induced weight gain (Álvarez-Jiménez et al., 2008) concluded that healthy living interventions for this population are effective, although the effect size was rather small, with an average reduction of about 4%...
of body weight. Only two of the interventions reviewed by Álvarez-Jiménez et al. were for first-episode psychosis, many of the studies had small samples, and some failed to describe their interventions adequately. Our own systematic review (HELPER team, 2008) of 12 trials, focussed on reduction in BMI, which we would argue is a better outcome measure than weight as there is less heterogeneity. We concluded that while some interventions have been effective, more work is needed to determine the ideal content of interventions. Analysis of group versus individual interventions suggested an advantage for individualised interventions, and evidence is emerging that interventions with a supervised exercise component may be superior to those in which exercise is merely prescribed or is absent. There is little evidence on long-term effects of the interventions, but what evidence there is suggests that the difference between treated and control participants tails off after about 2 months, suggesting a need for booster sessions and longer term follow up. A final observation is that none of the interventions in the literature to date was explicitly informed by any theoretical framework or model of behaviour change. We concluded from our literature review that there is a need for a phase-specific intervention to reduce BMI; that at least some components of the intervention should be individualised; that the intervention should include supervised exercise; that there should be post-intervention booster sessions; and that there should be long term follow up.

According to Blackburn (1995), health benefits can be seen with a body weight reduction of 5% or more, so this should be the minimum goal for any intervention. For a man aged 16–24 of UK average height (177 cm) (Health Survey for England 2006, Latest Trends) with a BMI in the overweight but not obese range of 27 (weight 84.6 kg), a loss of 5% of body weight (to 80.36 kg) would equate to a reduction in BMI of 1.35 points. We therefore decided that, in order for our intervention to have clinically meaningful effects, we should aim for a reduction in BMI of at least 1.5 points.

The most important features to emerge from our interviews with service users were that there is a general willingness to undertake a healthy living programme, that the intervention must be accessible in terms of both travel and cost, but that the actual place of the intervention was of less importance. Some service users would prefer a group intervention, with social activities, while others would prefer individual sessions. Mainly for reasons of time constraints, case managers were not enthusiastic about delivering the intervention themselves, and felt that whoever delivered the intervention would need additional training. There was agreement that the intervention needed to target both diet and exercise and that it needed to be enjoyable and client-centred. In order to further tailor the intervention to the views of service-users, we have decided to use people with lived experience of early psychosis as facilitators for some of the group activities.

Leventhal’s self-regulatory model (Leventhal, Nerenz & Steele, 1984) states that when people encounter a threat to their health (such as the threat posed by weight gain in first-episode psychosis) their behavioural response to that threat is generated by their personal perceptions or model of the threat. These personal perceptions are formed from both concrete perceptual experiences (such as previous experience of the health threat) and from abstract information (such as information from health care professionals and health education) and, if maladaptive, are more amenable to change if information comes from a both concrete and abstract sources. Threats to health may be actual (such as a current illness) or future risks (such as the threat posed by weight gain). The self-regulatory model suggests that it is important to take into account people’s personal models when prescribing (or developing collaboratively with patients) treatment programmes aimed at reducing health threats. Empirical work over the years since the model has developed has shown that health threats are conceptualised along a number of underlying dimensions, which can now be measured (Moss-Morris et al., 2002), and used to inform individualised treatment programmes. Furthermore, recent work has started to adapt these established measures to enable the assessment of risk perceptions of potential threats to health (Cameron, 2008; Figueiras & Alves, 2007), and the intention to adopt preventive behaviours. The model prescribes the setting of goals, the use of well-specified action plans, and emphasises the roles of appraisal and feedback in modifying perceptions and behaviours. All of these elements are to be incorporated into our intervention.
Our intervention will take account of ethnic differences in diabetes and cardiovascular disease risk and of cultural factors with the potential to impact on both exercise behaviour and dietary change. There is evidence that BMI cut-offs for overweight, obesity and health risk are different in South Asian and other populations. Specifically, members of the South Asian population begin to be at risk of diabetes and cardiovascular disease at a lower BMI (≥ 24) than do members of the general population in the UK (Huxley et al., 2008; Obesity in Asia Collaboration, 2007) and we will take account of this when determining our entry criteria and when evaluating progress during the intervention. Exercise prescriptions will be agreed with the participants, and participants will be invited to involve family members in their exercise programme should they so wish. Dietary recommendations will take account of cultural and ethnic differences in diet; dietary recommendations will be based on food groups and will be made in consultation with dieticians experienced in working with culturally diverse populations. We will endeavour to make our intervention materials relevant, comprehensible and acceptable to participants from different backgrounds. After the intervention, we will seek the views of participants on its acceptability.

2.3 Summary
To summarise, our Phase 1 work has led us to design a twelve-month healthy living intervention for patients who have experienced their first episode of psychosis in the past 3 years, who are attending an early intervention service, and who have a BMI of ≥ 25 (24 for people of South Asian origin). The intervention will focus on increasing activity and improving diet, and will:

- aim to reduce BMI by 1.5 points at six months after the start of the intervention and to maintain this loss at the one year follow up;
- consist of a mixed programme of individual and group sessions delivered over the first six months (the intervention proper);
- provide a booster session in the second six months to reduce the risk of relapse;
- contain an exercise component;
- be delivered by a support time recovery worker (STR worker) who will utilise community resources and other professionals already working with this population, and will be assisted by service-users or ex service-users acting as group facilitators;
- tailor treatment to patients own personal perceptions of weight gain and the risks associated with it;
- be adapted to take account of cultural factors.

3. Objectives of the trial
The objectives of the INTERACT Trial are

1. To determine the clinical effectiveness of the intervention in reducing body mass index (BMI) by 1.5 points
2. To assess the long term effects of the intervention at 12 months post-baseline.
3. To assess the cost effectiveness of the intervention
4. To assess the acceptability of the intervention to participants

4. Design and brief outline of trial
This is a randomised controlled trial of a 12-month Healthy Living Intervention incorporating a booster session plus standard care versus standard care alone in an Early Intervention Service for patients with a first episode of psychosis in the past three years. The unit of randomisation will be the individual patient. The intervention will contain both individual and group components, the components of which will be delivered on a rolling programme by a specially trained Support Time Worker (STR), working with ex service-user facilitators. The STR worker may also enrol the assistance of others already working with this group (such as occupational therapists) where appropriate. The primary outcome will be change in BMI at
12 months post-baseline; secondary outcomes will include activity levels, a measure of quality of diet, and relapse of psychosis. The components of the trial are described in more detail below.

5. Participants

5.1 Inclusion criteria
The following people will be eligible for the trial:

1. aged 16 to 35 years
2. with a diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief reactive psychosis, or psychosis not otherwise specified, determined using a checklist of criteria and review of case notes (OPCRIT http://sgdp.iop.kcl.ac.uk/opcrit/)
3. first episode of psychosis occurred within the three years preceding the trial
4. current user of an early intervention service
5. have stable accommodation (i.e. not street homeless or roofless)
6. able to give informed consent
7. have a BMI of $\geq 25$, or a BMI of $\geq 24$ for service users from the South Asian community (Huxley et al., 2008; Obesity in Asia Collaboration, 2007)

5.2 Exclusion criteria
People will be excluded from the INTERACT trial if they:

1. have a diagnosis of substance dependence or abuse as determined from a review of case notes. Sub-diagnostic levels of substance use or abuse will not exclude people from the trial.
2. have a significant history of organic factors implicated in the aetiology of psychotic symptoms.

6. Recruitment procedures

The INTERACT trial is part of the HELPER programme of three clinical trials for people recovering from a first episode of psychosis, the other two streams being a cognitive remediation intervention and an intervention to reduce cannabis use. An integrated approach to recruitment across all three streams will be used. Research assistants attached to each trial will work as a team and will recruit eligible participants for all three trials. A trial manager will coordinate the work of the research assistants.

Patients will be recruited from the Lancashire and Mersey Care Early Intervention Services. Mental Health Research Network Clinical Studies Officers, together with members of the research assistant team will approach all Case Managers working for these services and ask to screen their entire caseloads for potentially eligible patients, using inclusion criteria 1–7 above. Having identified the list of possible patients, this will be shared with the case manager to check that criteria 1–7 are likely to be fulfilled. In particular, it may be necessary to obtain supplementary information on BMI. At this stage a preliminary decision will be made as to which patients might be suitable for each of the three HELPER programme trials so that patients can be approached about potential participation in a specific trial. Patients who are known to have a substance use problem will be approached about the cannabis use trial. Patients with a BMI of $\geq 25/24$ and no known substance use problem will be approached about the INTERACT intervention. Patients who are awaiting cognitive therapy will be approached about the cognitive remediation intervention. Patients will be allocated a referral number for each trial at this point.

Participants identified as potentially suitable for the INTERACT trial will be given (by their case manager at a routine meeting) or sent (in the post) a copy of the INTERACT trial patient information sheet, together with a covering letter introducing the trial from their case manager. Ideally, we will encourage case managers to speak personally to potential patients about the trial and to obtain written consent from the
patient for a member of our research team to contact him or her. To facilitate good working relations with case managers, our research assistants will be based with the case managers for at least part of the working week. In addition, the covering letter will have a tear off slip which potential participants can return to the research assistant to give permission to be contacted by telephone or letter, or in person at the Early Intervention Service offices, to discuss the trial further. Potential participants will have the opportunity to ask questions about the trial and will have at least one week to decide whether or not they wish to enter the trial.

If the patient agrees to be assessed, an appointment for an assessment interview will be made with the research assistant. Assessment will take place either in the patient’s home, at the Early Intervention Service, or in another location of the patient’s choice, by agreement. Potential participants under the age of 18 will have the opportunity to have a parent or guardian present during the assessment. Before the assessment begins, the trial will be explained again, another opportunity to ask questions will be given, and written informed consent to participate will be obtained. For participants under the age of 16, the written informed consent of a parent or guardian will also be required.

If the patient fulfils criteria for the INTERACT trial, he or she will be randomised into this intervention (see below). If the patient does not fulfil criteria for the INTERACT trial, he or she will be given information about the other two HELPER trials.

The INTERACT intervention will be offered as a ‘rolling programme’ of individual sessions with the option of a range of group sessions. Patients will be able to join the optional group sessions at different points in the programme. This will prevent the long delays which could occur for some patients while waiting for a group to be recruited.

7. Randomisation procedure and protection against bias

Group allocation will normally take place within one day after the baseline assessment has been carried out. Patients will be allocated on an individual basis by a person or organisation independent of the trial, by referring to one of two randomisation lists produced using PsyGrid before the start of the trial. The procedure will use randomised permuted blocks, with randomly varying block sizes of 2, 4, 6 and 8, after stratification for whether or not the patient has started to take olanzapine or clozapine in the past 6 months. There will therefore be two strata in total, and a separate randomisation list for each. A standard operating procedure for the randomisation of patients will be written. The research assistant who performed the assessment will supply the randomisation service with patient’s name and date of birth, and whether the patient has started to take olanzapine or clozapine in the past 6 months. The patient will be allocated to the next vacant position on the appropriate randomisation list, which will give the patient a unique study identifier and group allocation.

The patient’s study identifying number and group allocation will be informed to the STR worker and to the patient, but only the study identifying number will be supplied to the research assistant, who will remain blind to patient randomisation from this point on. To ensure that researchers remain blind to patient allocation, a blinding protocol will be adhered to by both researchers and STR workers. Level of blindness will be assessed by asking researchers to ‘guess’ the patient’s allocation after they have completed the final assessment.

A letter will be sent to the patient’s Case Manager, informing him or her of the arm to which the patient has been randomised.
8. Detailed description of the treatments, protocol for the intervention, therapist intervention manuals and patient materials

8.1 The active intervention
The INTERACT intervention will comprise of 8 individual sessions over a 12 month period with an emphasis on facilitating participatory exercise and dietary change through the development and implementation of patient led action plans. These sessions will be delivered by STR workers who will be trained in the delivery of the intervention. The STR workers may also be able to access other workers (e.g. occupational therapists) as a resource for the intervention. To facilitate implementation of exercise and dietary change a range of optional active group sessions (e.g. football, walking, netball groups, and a cooking group) will be offered by the STR worker for those who prefer a group based activity. The STR workers will be assisted in the running of the groups by service user or ex-service user facilitators. To optimise engagement, choice and self management a booklet will be given to all participants providing educational advice, action plans, goals, details of the group sessions, healthy eating recipes on a budget etc. A strong emphasis will be placed on maximising carer/family engagement.

8.1.a Individual sessions
The intervention will comprise a total of 8 individual sessions, 5 sessions in the first 3 months followed by 2 sessions in months 4–6 and a final session in months 10–12 to ensure gains are incorporated into the individual’s lifestyle. In brief sessions 1 and 2 will focus on the elicitation of health beliefs and the collaborative development of individualised action plan and goals for change. A focussed discussion will elicit the goals for change, goals will be collaborative, measurable and feasible such as ‘To go to the gym 3 times per week’, ‘to increase the number of fruit and vegetables I eat by 50%’. Such goals will take account of previously and currently enjoyed activities which are exercise related, whether the participant has a preference for group or individual activity, carer/family involvement to assist with changes, and information on local activities which are geographically accessible and affordable. Sessions 3–5 will focus on the implementation of the action plan, (and where agreed the inclusion of family/carer involvement). Collaborative problem solving will identify and facilitate solutions to barriers of implementing the action plan. These sessions may also involve the STR worker accompanying clients to a particular activity for the first time (ie gym, swimming etc) to maximise implementation. Sessions 6 and 7 will focus on progress and monitoring of the goals stated in sessions 1 & 2 and adaption’s made as necessary. Session 8 will focus on working with the user to ensure that implementation is embedded within their everyday routine.

8.1.b Group Sessions
In addition to the individual sessions a range of optional group sessions will be delivered by the STR worker and co-facilitated by a service user on 3–5 occasions weekly for 2 hours and will incorporate some of the following ‘team exercise games’, lunch groups involving cooking and eating a healthy lunch, country walks, etc. Families and carers will be welcomed to attend the groups. Group activities will alternate between different geographical locations to maximise participation.

8.1.c The INTERACT Intervention Booklet
A healthy living intervention booklet will be given to all participants and will provide accurate information about healthy living, including governmental guidelines on exercise and diet, strategies for implementing such changes into usual daily routines, culturally varied recipes, barriers and facilitates to implementing healthy living which are specific to the participants mental health problems including fatigue and motivation, a section for families and carers and information of local activities. The booklet will have a Flesch readability ease score of between 60 and 70 and will be translated into Urdu.
8.1.d. Training of STR workers and facilitators, training materials and training handbook
Training for the STR workers will be provided by the trial team and a user and will consist of a 3 day intensive training programme. On the third day of this training, the STR workers will be joined by service user facilitators who are going to be working with the groups, and who will receive one day’s training. The training will be accompanied by a training handbook with detailed session by session outlines. The training will focus on all aspects of delivering the intervention from initial assessment, elicitation of health beliefs, developing collaborative action plans and goals, engaging family/carers, monitoring and collaborative problem solving to overcome barriers to implementation. A significant portion of the training will be spent practising the above skills using fictitious but typical cases to enhance learning and skill. In addition the STR workers will receive training on the running of groups.

8.1.e. Supervision of STR workers and facilitators.
Clinical supervision for the STR workers and service-user facilitators will be provided on a two weekly basis by members of the research team (TB, AW, KL).

8.2 Standard Care
The EIS works individually with each service user and his or her family to address problems/needs that are identified during his or her assessment/reassessments; all service users have enhanced care coordination and all should have a specific care plan personalized to their needs. Each service user would be seen on a regular basis; this may be weekly, fortnightly or more or less frequently by his or her case manager depending on the stage of the intervention and the need.

The case managers are supported by support time recovery workers who are commissioned and supervised by the case managers to do specific work, often for time limited periods. The service users are also offered cognitive behaviour based interventions by case managers. Case managers may consult with and obtain input from psychological therapists/psychologists who may themselves also be involved in delivering formal CBT.

9. Assessments and measures
9.1 Timing and administration
There will be three assessment points: Baseline assessment prior to randomisation into the trial; at 6 months; and final assessment at the end of one year. The primary outcome point will be at one year.

Assessments will be administered by the trial research assistant(s). While the majority of measures are self-report measures, in accordance with a blinding protocol every effort will be made to keep research assistants blind to randomisation codes so that post-intervention and long-term follow up assessments can be carried out blind to treatment allocation. Any unblindings will be recorded, and we will the degree of blindness maintained at the end of the trial (see Section 7 above).

9.2 Measures
The primary outcome will be change in BMI at one year post-baseline. This will be determined by measuring the participants’ height at baseline assessment and weighing the participant using the same set of scales at each assessment. The formula weight in kg/height in metres² will then be applied to determine BMI. The intervention will be deemed successful if a patient has reduced his or her BMI by at least 1.5 points at one year follow up.

Secondary outcomes will be: weight loss at 6 months (ie end of the intervention proper); change in waist circumference, level of daily activity as measured by a standard activity level measure which has been validated for use in this population (short form IPAQ, Craig et al., 2003; Faulkner et al., 2006); adherence to the agreed exercise programme; relapse of psychosis, as determined from a review of case notes; health
status and quality of life as measured by the EQ-5D (Rabin & de Charro, 2001) and the MOS SF-36 (Ware & Sherbourne, 1992); food frequency diary, with cultural adaptations (Crozier et al., 2008).

Measures of predicted process variables and mediators of change will be; a measure of representations of weight gain and intentions to take preventive/remedial action (Cameron, 2008; Figuieras & Alves, 2006); a measure of perceptions of antipsychotic medication (Fialko et al., 2008); Depression will be measured using the Calgary depression scale (Addington et al., 1996) as a potential predictor of response to the intervention; reduction in depression may also be an outcome of interest. We will also measure adherence to medication (Brief Adherence Rating Scale, BARS; Byerly et al., 2008) and keyworker rating of adherence to medication on four point scale (Fialko et al., 2008).

9.3 Schedule of assessments and measures

Table of assessment measures for HELPER Interact Trial

<table>
<thead>
<tr>
<th>Assessment measure</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
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</thead>
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<tr>
<td>Level of daily activity (short form IPAQ)</td>
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</tr>
<tr>
<td>Relapse of psychosis from notes</td>
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</tr>
<tr>
<td>Adherence to agreed exercise programme</td>
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<tr>
<td>Quality of life (EQ-5D)</td>
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<td>Health status (SF-36)</td>
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<td>Food frequency diary</td>
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<td>✓</td>
</tr>
<tr>
<td>Economic Analysis</td>
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</tr>
</tbody>
</table>

9.4 Training and supervision of research assistants

Our research assistant(s) will be trained to administer the outcome measures in a standardized way. They will receive regular debriefing and supervision which will focus both on the integrity of the assessment procedures and on any health and safety or other issues arising from the assessments.

9.5 Risk assessments and health and safety

Risk assessments will be carried out prior to each assessment visit, in accordance with the procedures of the Early Intervention Services from which the patients are recruited. No RA will visit any patient in the absence of an up-to-date risk assessment. In order to maintain blindness, RAs will not have direct access to risk assessments.
10. Power analysis

Our trial is powered on the basis that a reduction in BMI of 1.5 points would be of clinical significance, and would be feasible to achieve. Our systematic review of weight loss interventions suggests a common standard deviation for change in BMI of 2 points, giving an anticipated effect size of 0.75. Using a simple t-test to compare intervention and control groups, we would require a total sample size of 78, or two groups of 39, for our finding to have 90% power to be significant at the p < .05 level (nQuery Advisor). Our systematic review shows that the anticipated drop out and loss to follow up rate will be low, at around 10%. Allowing for loss to follow up of 10% of the sample recruited, we would require 86 patients at baseline (43 allocated to each group).

Because the intervention arm of our trial includes optional group components, there is some potential variability in the actual intervention received by participants allocated to the intervention arm. To account for the possibility that some participants will attend groups and others will not, thus adding an additional factor to be taken into account in the analysis, we have increased the sample size suggested by our power calculation by 20% to 104 (52 in each group).

11. Economic assessment

The aims of the economic evaluation will be to explore whether the intervention has the potential to be cost effective and inform the design of a Phase III RCT. The costs will include the costs of the intervention (staff, facilities, equipment and materials), the costs of primary, community and secondary health service use, the costs of other social care service use and the costs of alternative and personal health expenditure. The data will be collected from patients using service use forms adapted from other studies. Unit costs will be collected from local and trial accounts (to estimate the costs of the intervention) and published databases (PSSRU, DH Reference costs). The unit costs will be supplemented by published literature where necessary. The main outcome for the analysis will be quality adjusted life years (QALYs). Two estimates of QALYs will be calculated from health status measured the EQ-5D and by the SF36 and associated population tariffs. Service use and health status data will be collected at each scheduled assessment from baseline to the end of follow up. The analysis plan for the economic assessment can be seen at 12.3b.

12. Analysis plan

12.1 Data entry and checking

Data spreadsheets will be set up by IT staff at the Mental Health Research Network. Data will be entered into data spreadsheets (one for each time point) by research assistants as they collect it. Data entry will be centralised using PsyGrid software so that RAs from each of the three HELPER trials can enter data online onto a central server. The primary outcome measure (weight and height before and after the intervention) and secondary outcome measures (weight at one-year follow up, activity levels, measure of quality of diet) will be double entered by two research assistants. Other data will be checked and cleaned by the research assistant before analysis.

12.2 Data protection and confidentiality

Paper copies of questionnaires will be stored in locked filing cabinets at the University of Manchester. Details of patient randomisation will be stored separately from all other data and password protected.

Monitoring arrangements
12.3 Analysis

12.3a Analysis of primary and secondary outcomes and process measures
Analysis of the primary and secondary outcome measures will be as randomised, i.e. on an intention to treat basis. Longitudinal data will be modelled using a mixed-effects model. Analyses to estimate treatment effects will be variations on analysis of covariance (depending on whether the outcome is binary or quantitative), with covariates including whether the patients is taking olanzapine/clozapine or not and baseline BMI. The effects of the optional group therapy will be explored using recently-developed causal inference methods to evaluate the role of mediators and other process variables in complex intervention studies – see TenHave et al., 2007; Dunn & Bentall, 2007; Emsley, White & Dunn, 2009.

Distinguishing between attrition from treatment and attrition from the trial is rarely shown in academic papers. In keeping with the philosophy of ITT we will make every effort to follow people up regardless of whether they have been lost to treatment and distinguish between attrition (adherence) from treatment and attrition from the trial. As those who are not adherent with the treatment protocol tend to be less adherent with the assessments protocol, we will establish special procedures and make targeted efforts to assess the treatment dropouts at all scheduled time points.

Where data are missing, they will be modelled on the assumption that they are missing at random. Logistic regression will be used to test the validity of this assumption, and to calculate a probability of providing complete data, with baseline variables as predictors. These analyses would then be used to create inverse probability weights for subsequent analyses on outcome variables.

The effects of possible mediating variables will be tested by assessing their effect on outcome and on the significance of the treatment effect when they are added as additional covariates in the above analyses.

12.3b Analysis of economic data
Statistical analysis (regression, structural equation modelling) will be used to identify key covariates and potential mediators or moderators of costs. Cost effectiveness acceptability analysis will be used to explore the potential cost effectiveness of the intervention compared to standard care. All comparisons of costs and QALYs, and all cost effectiveness acceptability analyses will be adjusted for baseline covariates, mediators and moderators. The QALYs measured by the EQ5D and SF36 will be compared to assess whether they affect the results of the cost effectiveness acceptability analyses and identify whether one is more likely to be reliable, relevant, sensitive and valid than the other in this population, for this type of intervention.

13. Adverse events procedure and withdrawal of patients from the intervention
Patients will be withdrawn from the intervention under the following circumstances:

- development or exacerbation of a medical condition which means that the patient is unable to continue, or that continued participation in the trial endangers the patient’s health

- Withdrawal from intervention does not have to mean withdrawal from the study. Follow up assessments will still be made provided the patient is willing and able to undertake them, and every attempt will be made to maintain the blinding of the assessor.
14. Time schedule for trial

Ethical approval will be sought in January 2009. The STR worker will be trained from March to June 2009, and resources gathered (directory of local community resources, contacts made with other workers etc.) to design and implement the rolling programme of activities. Arrangements will be put in place to start recruitment from April 2009. Patients will be randomised into the trial over a period of eighteen months, starting in June 2009 and ending in December 2010. The intervention will last for 12 months, so that the last intervention groups will finish at the end of December 2011, with the last follow up assessments occurring within one month of that date.

15. Trial governance and management

15.1 Ethical approval
Ethical approval will be sought from the appropriate NRES committee.

15.2 Insurance and indemnity
A procedure to ensure the health and safety of trial workers will be appended to the protocol.

15.3 Trial management and oversight
Members of the HELPER INTERACT research team will meet monthly, and will report to the HELPER Programme Management group at their three-monthly meetings.

There will be two independent committees overseeing the work of the entire HELPER programme – a Trial Steering Committee (TSC) and an independent Data Monitoring and Ethics Committee (DMEC).

The DMEC will consist of members external to the study team including a statistician, a clinician and an expert in health services trials. A DMEC report template will be devised for reporting purposes and agreed by the DMEC committee prior to the commencement of the study.

16. Protocol amendments

Any amendments to the protocol which take place after the trial starts will be recorded in this protocol.

17. Ancillary studies

The agreement of the trial management team will be necessary for the adoption of ancillary studies. Such studies might include an investigation of the impact of the programme on significant others of participants.

18. References


nQuery Advisor. URL: [http://www.statsol.ie/nquery/nquery.htm](http://www.statsol.ie/nquery/nquery.htm)


OPCRIT [http://sgdp.iop.kcl.ac.uk/opcrit/](http://sgdp.iop.kcl.ac.uk/opcrit/)


Appendix 11 The Rethinking Choices After Psychosis (ReCAP) trial protocol

**Title:** A phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis.

**Aim of study:** To evaluate a phase-specific psychological therapy (intergrated Motivational Interviewing and Cognitive Behaviour Therapy, MiCBT) designed to reduce cannabis use in people who have recently experienced a first-episode of psychosis. For young, early psychosis clients we hypothesise that a brief intervention (12 sessions) is as efficacious as longer term therapy (24 sessions) when compared with treatment as usual.

**Background:** People with psychosis have a higher rate of substance use disorders than comparable non-psychotic comparison groups. The rate is high amongst young people who have recently had their first episode of psychosis (Barnes et al., 1999; Lambert et al., 2005). In this population (FEP), cannabis is the most commonly used illicit drug, with typical rates of 35–45% for current cannabis use (Barnes et al., 2006; Lambert et al., 2005; Wade et al., 2006). Young people with psychosis who use cannabis are at increased risk of: delayed remission, relapse, suicidal behaviour, violence, social instability and homelessness (Barnes et al., 2005; Cleghorn et al., 1991; Linszen, 1994, Sorbara et al., 2003; Verdoux et al., 2001). These risks are present even at levels of consumption that would be considered unremarkable in the general population, suggesting that psychosis brings an increased sensitivity to cannabis (Curran et al., 2002; Bellack et al., 2007).

It is particularly worrying when problematic cannabis becomes ingrained in the period immediately after a first episode of psychosis (Bellack et al., 2007). It is widely believed that the pattern of illness established during this ‘critical period’ determines the long-term prognosis of the condition (Birchwood et al., 1998). Thus repeated psychotic episodes, induced by cannabis use, may increase the risk of treatment resistant symptoms, and precipitate an irreversible decline in social functioning, leading to life-long reliance on health and welfare services.

Unfortunately people with psychosis and substance misuse (‘dual diagnosis’) tend not to be well served by mental health services, even though treatment of dual diagnosis is a major NHS priority (Weaver et al., 2003). Care often arrives too late in the day, after treatment resistance has set in, problematic patterns of substance misuse are well-established and motivation for change is low (Teeson et al., 2000; Baker et al., 2002). Our own experience concords with the literature: in our earlier evaluations of therapy for people with dual diagnosis, we found that entrenched co-morbid substance use problems required intensive long term contact with a therapist (i.e. from 9–12 months duration) (e.g., Barrowclough et al., 2001; Haddock et al., 2003). Thus, there is a strong case for targeting people at an earlier stage of the illness when cannabis use is not so well established, and the deterioration consequent on prolonged use has not set in.

As yet there are no interventions with clearly demonstrated acceptability, efficacy and effectiveness for people with substance misuse following a first episode. However, there are some indications that it may be easier to motivate patients to reduce cannabis if we intervene at an early stage of the psychosis. For example, in Melbourne, Australia it has been reported that 50% of young people using cannabis at admission to early intervention services voluntarily cease use within the first 6–10 weeks (Edwards et al., 2006). This research group recently reported a clinical trial where 47 FEP patients using cannabis in the 4 weeks prior to assessment were randomised to 10 sessions of either psycho-education or a cognitive behavioural intervention. Over time there was significant reduction in cannabis use in both groups was found. Methodological issues limit the generalizability of this trial: the sample size was small and, there was no treatment as usual control group, meaning that we cannot measure the intervention improvement against any spontaneous reduction that occurred without treatment. Additionally, in a recent review of

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interventions for cannabis use in non-dual diagnosis samples, it was concluded that ‘response rates, particularly abstinence from cannabis, leave much room for improvement’ (Denis et al., 2006). Thus it remains unclear whether brief psychological intervention is effective for this client group.

To take forward this area of research we propose to evaluate two hypotheses, concerning the treatment of cannabis use in people who have recently had a first episode of psychosis. The first hypothesis is that a long term intervention (24 sessions delivered over 9 months) will be more effective in reducing cannabis use than treatment as usual. The second hypothesis is that a brief intervention (12 sessions delivered over 4.5 months) will be as effective as the long-term intervention.

**Summary of trial and proposed trial design**

*Summary of trial:* People who have had a first episode of psychosis and who are under the care of an EIS service in one of the participating sites, who also have a co-morbid cannabis misuse or dependence problem will be randomly allocated to one of 3 conditions:

1. Long (9 months) treatment in addition to standard psychiatric care
2. Brief (4.5 months) treatment in addition to standard psychiatric care
3. Or standard care alone (SCA) – ‘Treatment as Usual’.

The therapy – integrated Motivational Interviewing (MI) and Cognitive Behaviour Therapy (MiCBT) – consists of MI to increase motivation for change, and cognitive behaviour therapy to assist the implementation of change and relapse prevention strategies. The MiCBT which patients receive will be matched to their stage of change during the treatment phase.

*Proposed trial design:* A rater blind randomised controlled trial using geographically defined samples of patients from different localities to ensure good generalizability of the study. This is a pragmatic rather than explanatory trial carried out to evaluate the benefits of two levels of psychological treatment over standard available care.

*Planned trial interventions*

The integrated MiCBT will match the focus of therapy to the patient’s stage of change regarding cannabis use.

For all clients initially substance use will be approached within the context of the client’s lifestyle and mental health problems, and the intervention will be described as an approach to identifying helpful lifestyle changes (too much of an emphasis on cannabis use in the initial stages of the intervention may be detrimental to the motivational processes in clients not ready for change). With the client’s permission, later sessions will focus on examining the role of cannabis and how it relates to problems and desired goals. Using the motivational interviewing style, the therapist will seek to understand the client’s frame of reference and build up a shared model of how cannabis relates to their mental health and other life concerns. Once client commitment to change is secured, the therapist will assist the client to make a plan for cannabis cessation or reduction. Cognitive behavioural techniques will be used to assist with the implementation of change. These will include identifying and problem solving for high risk situations; CBT for coping with symptoms associated with substance use; and relapse prevention. Whilst the intervention will use a range of strategies to develop and consolidate the client’s motivation to reduce cannabis, we do not expect all clients to move through stages at the same pace and some may be unwilling to change their substance use. As noted below, these clients will be supported in selecting a goal that is of high priority for them whilst the therapist will seek further opportunities to review substance use within this context. The care co-ordinator will be invited to 3 meetings (beginning, middle, end of therapy) to ensure good communication between the intervention and the EIS.
From our previous studies, we anticipate that there will be considerable variation in the number of sessions participants opt to attend; that some patients will require assertive outreach (unlimited repeat appointments; flexibility in timing and location of sessions; tracking of change in residence) in order to maintain engagement; and that engagement may wax and wane over the treatment period. The number of sessions attended will be controlled for statistically in the analyses.

Mindful of the client’s stage of change regarding cannabis, for both Long and Brief conditions the therapist will attempt to progress through the following steps:

Building engagement – developing a relationship:

1. Discussion with client about current concerns and how they have arrived at current situation particularly looking at mental health issues. Development of a wants list and problem list looking at obstacles to progress and identification of how their life values fit within these.
2. Exploration of their explanatory model of psychosis (onset, symptoms and consequences). Feedback information from assessments to further explore their understanding.
3. Exploration of how cannabis use fits into life generally and then elicitation of understanding of how cannabis use fits into their explanatory model of psychosis.
4. Provision of information about cannabis and mental health, feedback of information from substance use assessments and where appropriate further monitoring of links between cannabis and mental health.
5. Development of a shared understanding/formulation outlining links between psychosis, difficulties in life and cannabis use.
6. Based on formulation, discussion of possible change options, including change in cannabis use, to address difficulties identified by client.
7. Development of a change plan. Whilst abstinence will be the primary target of intervention, it will be the client’s choice whether they wish to plan for abstinence, reduction including harm reduction, or no change in substance use. If the latter option is selected then the therapist will help the client to focus on a goal that is of importance to the client and where possible the therapist will use this alternative goal as a context in which to continue to review the role of cannabis use and to facilitate motivation for change.

Differentiating the Brief and Long Interventions: Clients in the Brief intervention condition will be offered up to 12 sessions of MiCBT over 4.5 months; clients in the Long term intervention condition will be offered up to 24 sessions over 9 months. Both interventions will attempt to progress through the 8 steps delineated above. However, the Long intervention will potentially allow:

- More time to work through all the above steps. Those who have low motivation may be unlikely to proceed through all the steps in 12 sessions.
- More time to develop the change plan and particularly the use of CBT within the plan.
- Where clients are unwilling to change their substance use, more time to work on alternative goals and to develop motivation for changing substance use within these different contexts.

The MiCBT treatments will follow written protocols developed in our previous studies (Barrowclough et al., 2008), and further modified for this study by making it phase-specific for the ‘critical period’ of early psychosis. Therapists will undergo initial training and then supervision throughout the trial, and were participants give permission, sessions will be audio taped for the purpose of rating treatment fidelity.

Standard care from the Early Intervention Services involved in the study is compliant with the Policy Implementation Guide and includes intensive case management, crisis response, behavioural family therapy, and cognitive therapy for persistent symptoms.
Procedures for recruitment
Staff will be informed about the study prior to its commencement via presentations to teams and information sheets etc.

Identifying potentially eligible participants
All clients within the EIS of participating NHS trusts will be sent a letter from the head of the EIS service outlining the study and containing the Patient Information Sheet. The letter will inform clients that a) some clients may be approached by their care co-ordinator to ask if they would be interested in finding out more details about the study from one of the research workers, b) any client wishing to find out more should let their care co-ordinator know and the care co-ordinator will then pass on their name to the research worker. In this way, all clients will have the opportunity to discuss the research with a research worker and find out if they are potentially eligible.

For service users who agree to be contacted, the research worker will discuss the study with them and ensure that they have available a copy of the information sheet. Those consenting to be screened will be asked to complete an initial screening interview to evaluate inclusion/exclusion criteria. The interview will consist of the drug screen section of the SCID pertaining to cannabis.

Recruiting participants
Those service users who give informed consent and who fulfil the screen criteria will be recruited into the study. Once the service user consents to participation, letters will be sent to their GP, consultant and key worker.

Allocation of participants to trial groups
The trial will involve patients from the Early Intervention Services of two large NHS mental health trusts (Manchester Mental Health and Social Care NHS trust and Lancashire Care foundation NHS trust). In order to avoid treatment centre confounding, participants will be randomly allocated within each of the trusts to the three groups (MiCBT and Standard Care Long; MiCBT and Standard Care Brief; Standard Care alone) after stratifying by variables believed to be predictive of treatment participation or outcome: gender and living with family vs. not living with family. Allocation will be done using randomised permuted blocks with a randomly varying block size and will be the responsibility of the trial statistician.

Sample size
Our primary outcome measure will be number of days abstinent using the Time Line Follow Back. In a comparison of the Standard Care Alone vs Long and Brief treatments, with a sample size of 45 in each group and allowing for 20% attrition, the study would have 80% power to detect an effect size of 0.7 (a moderate to large effect size) with a significance level of .05. This effect size would be the equivalent of a 20% difference in days abstinent between no treatment and treatment groups which is in line with data from previous studies.

For the secondary outcome of the GAF, our previous research has shown that if the intervention is successful we would expect to see an 8 point improvement on this scale relative to the control group. Assuming a standard deviation of about 12 at baseline, a sample of 45 participants in each of the three groups is required to have an 80% chance of detecting this difference in two separate comparisons (short intervention vs. control; long intervention vs. control) using a Bonferroni-corrected significance level of 0.025. Hence for this exploratory trial we propose a total sample size of 45 per group (135 in total).
Proposed methods for protecting against bias

Blindness: Independent and blind assessment of the groups will be carried out. Blindness will be maximised by ensuring patient data are stored in separate offices, locating research and therapy staff in separate offices, and third party management of appointments to avoid appointment clashes.

Reliability of raters: Independent assessors will have a training period to ensure that they meet an identified standard of competence and level of reliability on the instruments used for the outcomes. These standards will be monitored by the project team. Independent checks on inter-rater reliability to check for rater ‘drift’ will be carried out during the trial.

Treatment Integrity: Treatment fidelity and skilfulness for the experimental condition (MiCBT) will be ensured by a) using therapists who have prior experience of using psychological treatments with psychosis clients, b) using therapists who meet the British Association of Behavioural and Cognitive Psychotherapies criteria for accreditation, c) by having a 3 month training period for therapists, d) weekly supervision using audiotaped therapy sessions provided by a therapist experienced in delivering MiCBT to psychosis clients. All therapy sessions during the trial will be audiotaped subject to the patients’ consent to permit independent fidelity ratings of taped sessions. Treatment dose in terms of number of therapy sessions attended will be closely monitored and documented, with good attendance facilitated by patients being offered treatment at the location of choice (hospital, home, clinic); by assertive methods of patient tracking; by offering an unlimited (within time constraints of the treatment period) number of repeat appointments when patients fail to attend.

Inclusion/exclusion criteria

(a) Meeting DSM-IV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, or psychosis not otherwise specified using a checklist of criteria and review of case notes; and confirmation of this diagnosis using the Structured Clinical Interview for DSMIV Axis 1 disorders (see elaboration below)

(b) DSM-IV diagnosis of cannabis dependence or abuse using the appropriate sections of the Structured Clinical Interview

(c) A history of cannabis use of at least x1 day per week in at least half the weeks in the 3 months prior to assessment (Those who are misusing other illicit substances or alcohol will not be excluded)

(d) Age 16–35

(e) Having stable accommodation (i.e. not street homeless or roofless)

(f) Possessing sufficient English to reliably complete the assessments

(g) Able to give informed consent

(h) No significant history of organic factors implicated in the aetiology of psychotic symptoms.

Elaboration regarding criterion a

We acknowledge the complexity of diagnostic issues with recent onset psychosis. Clients with a diagnosis of Brief Reactive Psychosis will be included at the screening stage since often this develops into full Psychosis. Information from all such cases and any others where there is diagnostic uncertainty will be reviewed by the trial psychiatrists who will decide whether diagnostic criteria are met and those included will be further reviewed diagnostically at the end of the study.
Context of the research study
The proposed study is part of an NIHR funded programme of research ‘The HELPER programme: Healthy Living and Prevention of Relapse’. The programme focuses on developing interventions to target known risk factors for relapse and poor health, in young people with early psychosis. The interventions are linked by a common theoretical framework, the Self-regulatory Model of Illness Management and designed for optimum delivery by the national network of Early Psychosis Teams. The Self Regulation Model (SRM) (Leventhal et al., 1984) proposes that people are problem solvers whose coping strategies are attempts to close the gap between their current health (as they see it) and the best health state they believe they can achieve. As part of the research program we intend to collect data to determine how far the SRM can be applied to people with psychosis. Hence the inclusion in this study of measures common to the programme.

Outcome measures
To be completed by blind and independent assessors at baseline, 4.5 months, 9 months and 18 months.

(i) Primary outcome – Cannabis use change: Measures of severity and frequency of cannabis and other illicit substances derived from Time Line Follow Back (TLFB) will be used. The TLFB is the most well researched method of collecting reliable and valid retrospective self reports of daily substance use in terms of drugs (Fals-Stewart et al., 2000). We have found it to be acceptable and practical for use with this client group in a prior study (Barrowclough et al., 2001), with good concurrent validity in terms of independent ratings from patient case managers. The primary outcome will be frequency (calculated as change in percentage days abstinent (PDA)). A secondary outcome obtained from the TLFB assessments will be severity (percentage change in amount of use (PAU)) for cannabis relative to use at pre-treatment baseline. Information from collaterals including care co-ordinators will be used where possible using a similar TLFB method and the Clinician Rating Scales (Drake et al., 1996). Additionally the validity of the self reports will be assessed using hair analysis from a random sample of 25% of participants at pre, post, and follow up assessment points. Agreement to give a hair sample will not be an inclusion criteria.

(ii) Additional Secondary outcomes

Symptoms, functioning and service engagement:
Symptomatology: PANSS (Kay et al., 1989) to assess severity of symptoms; PSYRATS (Haddock et al., 1999) to assess distress regarding symptoms.

Relapse: Two methods of assessing the frequency and duration of relapse will be used: 1) number and duration of hospital admissions identified from hospital record systems, 2) number and duration of exacerbations of symptoms lasting longer than 2 weeks and requiring change in patient management (operationally defined, Barrowclough et al., 1999).


Service Engagement Scale (Tait et al., 2002): A 14 item measure of client engagement with services, with subscales of availability, collaboration, help seeking and treatment adherence. Disengagement with services is a widely acknowledged clinical problem with people with dual diagnosis. For 0, 12, 24 months.

Calgary Depression Scale (Addington and Addington, 1997): This is a 9-item scale designed to assess depressed mood in schizophrenia.
Deliberate self harm assessment: This is a structured assessment of whether an episode of near-fatal DSH has occurred in the previous time period (2 minutes), as used in the CUtLASS trial. (Both substance use and psychosis are risk factors for DSH).

Attitudes to Medication Questionnaire (Hayward, 1995).

Brief Illness Perception Questionnaire (Lobban et al., 2005).

Schedule for the Assessment of Insight (David, 1990).

Health status: EQ-5D and SF6D 9 (Brooks, 1996; Jenkinson & Layte, 1997). This measure is included for two purposes: Firstly, to explore the potential impact of the interventions on the health status and quality adjusted life years of patients. Secondly, to collect data to inform an economic analysis of the interventions included in the overall HELPER programme. For the full programme, we will examine how baseline characteristics of service users affect the cost effectiveness of the interventions and economic models (decision analytic models) will be developed to explore the potential impact of each of the interventions.

Use of health and social care services: Data will be collected from case notes and assessment about the range and frequency of health and social care service use. The data will be collected using the data collection forms developed for the MIDAS trial of combined motivational and cognitive behaviour therapy for people with schizophrenia and substance abuse. Again, this measure is included for two purposes: First to explore the potential impact of the intervention on the health status and quality adjusted life years of patients. Secondly, to collect data to inform an economic analysis of the interventions included in the overall HELPER programme.

Substance use outcomes:

Readiness to change: The Readiness to Change questionnaire (Rollnick et al., 1992).

Consequences of use: The Inventory of Drug Use Consequences (Blanchard et al., 2003) a 12 item self report questionnaire assessing consequences of use.

Cannabis Experiences Questionnaire (CEQ): A measuring the subjective experiences of cannabis (Barkus et al., 2006).

RESUS-D: Reasons for drug use questionnaire (Gregg et al., 2009).

Planned analyses

At eighteen month follow up we will assess the impact of the intervention on the primary outcomes. For the secondary outcomes we will use a one-tailed 0.1 level of significance, rather than the conventional 0.05 level of significance. This is because in this phase (exploratory trial) we are principally concerned to ensure that we do not reject an active intervention at this early stage of the development process. The study will permit us to calculate the likely sample size required for a definitive multi-centre trial.

All statistical analyses will be carried out using Stata (currently version 10). The general analysis strategy will be based on the intention-to-treat principle and will involve the use of analyses of covariance (the exact form depending on the nature of the outcome variable under consideration). Treatment effects will be assessed after allowing for stratification and other baseline covariates thought a priori to be predictive of outcome. Careful consideration will be given to the influences of non-adherence and drop-out.
References


