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Functional Imagery Training versus Motivational Interviewing for Weight Loss: A randomised controlled trial of brief individual interventions for overweight and obesity

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5	Functional Imagery Training versus Motivational Interviewing for Weight Loss:
6	A randomised controlled trial of brief individual interventions for overweight and
7	obesity
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39 **Functional Imagery Training versus Motivational Interviewing for weight loss:** 40 A randomised controlled trial 41 42

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Objective: Functional Imagery Training (FIT) is a new brief motivational intervention based on the Elaborated Intrusion theory of desire. FIT trains the habitual use of personalised, affective, goal-directed mental imagery to plan behaviours, anticipate obstacles, and mentally try out solutions from previous successes. It is delivered in the client-centred style of Motivational Interviewing (MI). We tested the impact of FIT on weight loss, compared with time- and contact-matched MI. **Design:** We recruited 141 adults with BMI $(kg/m^2) \ge 25$, via a community newspaper, to a single-centre randomised controlled trial. Participants were allocated to one of two active interventions: FIT or MI. Primary data collection and analyses were conducted by researchers blind to interventions. All participants received two sessions of their allocated intervention; the first face-to-face (1 hour), the second by phone (maximum 45 min). Booster calls of up to 15 mins were provided every 2 weeks for 3 months, then once-monthly until 6 months. Maximum contact time was 4 hours of individual consultation. Participants were assessed at Baseline, at the end of the intervention phase (6 months), and again 12 months post-baseline. Main outcome measures: Weight (kg) and waist circumference (WC, cm) reductions at 6 and 12 months. Results: FIT participants (N=62) lost 4.11 kg and 7.02cm of WC, compared to .74kg and 2.72cm in the MI group (N=58) at 6 months (weight mean difference (WMD)=3.37kg, p < .001, 95%CI[-5.2, -2.1], waist-circumference mean difference (WCMD)=4.3cm, p < .001, 95%CI[-6.3,-2.6]). Between-group differences were maintained and increased at month 12:

FIT participants lost 6.44kg (W) and 9.1cm (WC) compared to the MI who lost .67kg and

- 63 2.46cm (WMD=5.77kg, *p*<.001, 95% CI[-7.5, -4.4], WCMD=6.64cm, *p*<.001, 95%[-7.5, -
- 64 4.4]).
- 65 Conclusion: FIT is a theoretically-informed motivational intervention which offers
- substantial benefits for weight loss and maintenance of weight reduction, compared with MI
- alone, despite including no lifestyle education or advice.
- 68 Trial registration: ISRCTN registry: ISRCTN17292316 DOI
- 69 10.1186/ISRCTN17292316,18/07/2016.

70 Introduction

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Obesity is a leading cause of premature morbidity and mortality worldwide (1,2), but relatively small changes in weight (5% reduction) produce substantial health benefits (3–5). In individuals with overweight and obesity, a sustained reduction of only 2-5 kg reduces cardiovascular risk factors and can prevent progression to type 2 diabetes mellitus (6–8). Reductions in waist circumference bring their own health benefits, as excess abdominal fat increases diabetes risk fivefold in men with waist >102 cm and threefold in women with waist >88cm (9). Most weight loss programs focus on lifestyle education and peer support. These interventions produce some reduction in weight (10,11), but reductions are often reversed within 1-2 years: typically 40-50% of the original loss (12,13). Few studies document weight loss past the end of treatment (14). Maintenance of weight loss has been reported primarily after high-intensity lifestyle interventions that provided comprehensive weight loss counselling for up to 8 years (15), or in trials that delivered at least 6-18 months of extended care, with therapist contact, after the successful completion of a weight loss program (16). Current weight loss programmes place little emphasis on maintaining motivation (17), despite its central role in long-term weight control (18–20). Participants struggle to stay motivated when trying to maintain weight loss (21–23). Motivational interventions may therefore be as effective as skills based and educational approaches. Motivational Interviewing (MI) (24) is the best-established motivational intervention, but trials that include MI to support weight loss or physical activity typically achieve only modest effects (15,25,26). In consequence, MI's clinical significance is limited (25,27,28). There is a need for more effective motivational support. Two features of MI may produce sub-optimal impact. Participants are not taught how

to apply MI strategies by themselves, reducing its effectiveness in real-life decision situations

95 (29,30). The latest cognitive models of desire (29,31–33) and emotion (34–36) highlight the 96 critical role of episodic multi-sensory mental imagery in motivation (37–41), but MI remains

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a heavily verbal style of counselling.

Functional Imagery Training (FIT) (42) is a motivational intervention based on Elaborated Intrusion theory, which recognises the importance of vivid mental imagery in desires (32). FIT uses imagery to increase desire and self-efficacy for change. It is delivered in the empathic, accepting and respectful spirit of MI (24), trusting participants to be experts on themselves, and assisting them to identify their own goals and related behaviours rather than trying to convince them to adopt a preset regimen. The FIT protocol prescribes similar steps to MI (24): elicitation of the person's incentives for change, exploring discrepancies between core values and current behaviour, boosting self-efficacy, and, when people are committed to change, developing specific action plans for implementing this commitment. At each step, FIT also invites participants to develop personalised multisensory imagery to maximize the veridicality and emotional impact of each aspect. In essence, FIT is imagerybased MI, with a strong additional focus on training self-motivation through the use of imagery. When participants have developed plans for change, they transition into training to become their own FIT therapist, supporting their autonomy and ability to flexibly respond to self-management challenges in the natural environment using imagery. They are shown how to develop a cognitive habit of practising emotive goal-related imagery in response to cues from a routine behaviour, and encouraged to generate this imagery whenever motivation needs to be strengthened. Because imagery is more emotive than verbal thought (34–36), this vivid, affectively charged functional imagery sustains desire for change until each new behaviour becomes habitual. Functional imagery also interferes with cravings when temptations occur, by competing for working memory with craving imagery (43). Detailed episodic imagery that is firmly grounded in experience allows participants to anticipate

problematic situations, and plan and rehearse effective responses to them, increasing selfefficacy through 'symbolic practice' (44). Initial small-scale tests of FIT have shown benefits for reducing snacking (42).

In this study we recruited members of the public with overweight and obesity to compare the effects of MI and FIT on weight loss over 6 months of low-intensity treatment, and an additional 6 months of follow-up. We predicted that FIT would produce greater initial weight loss, because imagery amplifies the effective components of MI, and better maintenance at 12 months because FIT teaches the cognitive skills individuals need to stay motivated.

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Ethics and trial registration

Study approval was granted by the Faculty of Health and Human Sciences research ethics committee, University of Plymouth, on March 23rd, 2015. The International Standard Randomised Controlled Trials registration was http://www.isrctn.com/ISRCTN17292316, 18/07/2016.

Participants and recruitment

We advertised once for potential participants in the *Plymouth Shopper*, a free local community newspaper, reaching around 64,000 homes. The advertisement sought adult participants with a BMI ≥25 kg/m², to test motivational interventions for losing weight and becoming more active. Exclusion criteria were current pregnancy, diagnosed eating disorder, and failure to complete baseline assessments.

Sample size: A recommended sample size of 191 was estimated using G*Power 3.1.9.2, assuming power of .8 to detect a small effect size of .2 for between-group difference.

Design and overview

The trial was a single-centre, two-armed, single-blind, randomised controlled parallel design with matched therapist contact time, comparing FIT with MI (1:1 ratio of participants). The trial had 6 months of active intervention, followed by a 6-month follow-up with no therapist contact. Analyses are reported by intention-to-treat.

Randomisation and masking

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Participants completed demographic details and assessments before randomisation.

Participants were randomized to MI or FIT by the lead researcher using

https://www.randomizer.org/ (random pairs option). In the two post-treatment assessment sessions, research assistants (RAs) who were blind to the intervention group, collected and recorded primary outcomes. Participants were informed that new RAs would take their measurements, and were asked not to give away whether they were in the FIT or MI group. The lead researcher was present in the room and could verify and record if un-blinding occurred. Analysis of primary outcomes and quality of life was performed by an analyst who was blind to intervention and not otherwise involved in the trial.

Assessment measures

Primary outcomes were body weight, BMI and waistline. Weight (kg) was measured in street clothes, with shoes removed, using Omron BF511 Family Body Composition Monitor. Height was measured to the nearest centimetre, allowing calculation of BMI (kg/m²). For waistline measurement, participants removed coats and sweatshirts, but no other clothing. Waistline was measured to the nearest centimetre, at the height of the umbilicus, using a tailoring tape measure.

A secondary outcome was the global quality of life, measured using the 1-item Global Quality of Life Scale (GQOL; 43). Participants in both groups were asked if they would recommend the treatment they had been allocated to a family member, friend or colleague.

We collected data on participants' experiences and process variables, including frequency of motivational cognitions, self-efficacy for diet and physical activity, self-reported diet and physical activity. These results will be reported separately.

Interventions

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Both interventions were delivered individually by the lead author. Face-to face sessions were all conducted in the same counselling room on the University of Plymouth campus. Session 1 immediately followed the collection of baseline assessments and randomisation, and lasted 1 hour. Session 2 (approximately 35 min) was delivered by telephone a week later. Participants then received fortnightly 5-15 minute-long 'booster' phone calls until 3 months, followed by monthly calls to 6 months post-baseline.

We developed scripts to guide delivery of MI and FIT and ensure treatment fidelity and consistency (available from the authors), but the order of segments was flexible and guided by the participant's needs and responses, in keeping with the spirit of MI. Active listening (open questions, affirmation, simple and complex reflections, summarising) was used in both treatments. The initial session of MI and FIT had the same general structure. incorporating a negotiated agenda, discussion of the treatment allocation, assessment feedback, existing or potential goals, incentives for adoption of those goals, and past successes with weight loss efforts. The therapist checked degree of goal commitment. Once participants were committed to behaviour change, they developed a plan for action over the following few days, including strategies to address potential barriers to its implementation.

Session 2 reviewed and developed the themes from Session 1, in the light of experiences since the initial session. Booster calls provided opportunities to review progress, reaffirm successful aspects of performance and incentives for behaviour changes, and set additional sub-goals. Exclusively in FIT, all sessions and booster calls included mental imagery exercises.

If participants had requested advice on diet or physical activity they would have been referred to the UK's National Health Service's (NHS) publicly available and accessible NHS Choices website which provides general information and advice on health, for example staying fit, losing weight, or beating stress (https://www.nhs.uk/pages/home.aspx). We did not have to refer anyone to this option however. Qualitative participant experience data will be published in a separate paper, delivering insight on how participants felt about not being provided with pre-set regimen, diets, or information and advice.

FIT

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After discussion of assessment feedback in Session 1, the therapist explained the rationale for using imagery and gave an experience of affectively-charged imagery. After discussing incentives for potential behaviour change, participants imagined these outcomes occurring, as specific future events that were created as vividly as possible. Similar images were elicited about past successes and about detailed plans for the coming days, including successful achievement of each step and success in reaching their ultimate goal. Participants nominated a routine behaviour that could prompt their imagery practice. They carried out this behaviour in the counselling room, while imagining their action plan and goal. They were also encouraged to practise imagery before engaging in their chosen behaviour, and offered the simple 'Goal in Mind' app (https://itunes.apple.com/au/app/goal-in-mind/id1289557359?mt=8; https://play.google.com/store/apps/details?id=com.goalinmind&hl=en) to download. They could use the app to upload motivational photos, tick off when they had remembered to do imagery practise (the app did not provide reminders), input a goal they would like to achieve

and access a five minute audio that guided them through imagining how they would work on

their goal today and how good it would feel to achieve it. The audio was emailed as an MP3 file if participants did not want to use the app, but wanted the audio to practise.

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Session 2 reviewed progress, including participants' efforts at practising imagery. Imagery was used to help solve any problems with progress towards their goal and to motivate new sub-goals.

Booster calls developed imagery about recent successes, problem solutions, or new goals behaviours. If required, additional imagery exercises included: 'Cravings Buster' (deliberate switching of attention from craving imagery to goal imagery) and 'Plateau' (reflecting on benefits experienced so far and exploring additional ways of working on goals). MI

The therapist did not explicitly evoke imagery, and avoided language that was likely to trigger it. Some additional questions were added to the manual, to ensure that the MI sessions had similar time and intensity as the FIT sessions. A few examples are: "When you think about that list of things, how does it make you feel?", "Would you mind summarising the things that are likely to get better if you change your behaviour?" and "Is there anyone who could help you follow it through?" MI participants were offered a goal sheet with the action plan they developed with the therapist in the first session; FIT did not have this. They took the goal sheet home and were encouraged to review their statements, goals and strategies, especially when they felt they needed extra motivation. Two examples of this additional exercise from the script are: "Would you like to write that down so you have a summary to take away?" and "If you need a bit of a boost to your motivation over the next few days, you could try reading that over to remind yourself about what you said." The sections were as follows: What I am going to do...Why I want to do it...How I'll do it...I know I can do it because.... Participants were encouraged to add to the sheet as their goals or reasons for change evolved.

During the booster calls, they were asked if they had added any new goals or ticked

off achievements on their sheet.

Intervention fidelity

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The therapist was trained in FIT by two of the creators of FIT and undertook a 3-day MI course. She attended weekly clinical supervision meetings with the senior author, to review individual sessions. A random 20% sample of initial FIT and MI sessions was rated on the Motivational Interviewing Treatment Integrity (MITI) 3.1.1 (46) by an RA not involved in the project. FIT sessions were rated on a 15-item checklist based on the manual. Additionally, two RAs listened to the session recordings independently and categorised them according to the intervention they thought the participants had received.

Procedure

Participants gave informed consent a week before their initial session. After completing demographic details and all assessments, they were randomly allocated to MI or FIT. The treatment sessions followed, as described above. After the first booster call, all participants were asked to complete reassessments of the expected process variables (results reported separately). At the end of treatment (6m), they attended a 15-minute post-treatment assessment session in the counselling room. Quality of Life was assessed via emailed questionnaire one week before this session. RAs blind to intervention measured waist and weight, and participants completed process measures online. They were told that the therapist would be available if they were experiencing distress (none took up this offer). Participants were reminded that they were entering the unsupported maintenance period and that the

therapist would be in touch 2-3 weeks before the final weigh-in, to arrange the appointment.

They received £15 for their time and travel.

At 12 months, participants returned for the final weigh-in. This session did not include self-report instruments. They received £5 for completing this assessment.

Data analysis

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Weight and waist circumference were analysed separately. To estimate differences between MI and FIT, outcome measurements were regressed onto baseline score (kg or cm), a time indicator (6/12 months), and a group indicator (MI/FIT), using linear mixed-effects models (47). These models also included baseline BMI and its interaction with time and group; baseline BMI was included because it captures additional information about the severity of participants' condition when entering the study. These models are analogous to repeated measures ANCOVA, but allowed us to make efficient use of all available data without imputation of missing values. Of primary interest were the between-groups contrasts for weight and waist circumference at 6 and 12 months. Tests of parameter values and other contrasts are reported with Satterthwaite approximation for degrees of freedom. In a secondary analysis, GOOL scores at 6 months were regressed on baseline GOOL scores, baseline BMI, group, and the interaction of baseline scores with group. Alternative model parameterisations, in which treatment effects were estimated as a linear slope from baseline to 6 or 12 months, produced equivalent inferences. To support probability statements about the average effect of FIT vs. MI, and likely prognoses of future participants selecting FIT or MI, we re-ran our mixed models using a Bayesian estimation procedure with pessimistic but weakly informative priors (48); full details are available in our data supplement, but for regression coefficients these priors were Gaussian, zero-centred, and with a scale adjusted to 2.5 × SD(y) / SD (Gabry, J., & Goodrich, B. (2016). rstanarm: Bayesian applied regression modeling via stan. *R package version*, 2(1).) Based on these models, we provide summaries of the posterior density for the average treatment effect, and for the predicted prognoses of new individuals selecting FIT or MI. All models appeared to converge satisfactorily based on visual inspection of MCMC traces and parameter R-hat statistics (49). All data and R code for the analyses presented here are available in an online supplement.

Economic costing:

We used Public Health England's weight management economic assessment tool No.2 (50), to estimate the increase in quality-adjusted life-years (QALY) associated with the additional weight lost by FIT participants at 12-months compared with MI.

Results:

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A total of 141 participants was recruited in the time available (March -May 2016). One hundred and 20 were randomised, 58 to MI and 62 to FIT. One hundred and 14 were included in the analysis of the 6-month follow-up, and 112 completed both 6 and 12 month follow-ups (Consort Diagram, figure 1; Table A in the supplementary materials). No statistically significant differences were found between groups at baseline (Table 1). 21 out of 58 FIT participants reported having used the app or audio when asked at 6 months, 25 out of 55 MI participants had continued to use their goal-sheet past the first MI session when asked at 6 months. [insert table 1]

MI and FIT fidelity checks

MI skills were rated on the MITI's (44) 5-point scale: 1: Never, 2: Rarely, 3: Sometimes, 4: Often, 5: Always. For MI, ratings for Evocation, Collaboration, Autonomy, Support, Direction, and Empathy ranged from 3.9 to 4.9 (median=4.5). For FIT, they ranged from 3.8-4.7 (median =4.5). For FIT, 15 session elements were rated as 0 absent, or 1 present. Totals ranged from 13-15 (median = 15). Independent raters correctly assigned 100% of audio recordings to intervention.

315 [insert figure 1]

To visualise changes in weight and waist, we plotted unadjusted means and 95% confidence intervals for each group. Figure 2 indicates that participants treated with MI experienced little to no reduction in weight or waist from baseline to either 6 or 12-month follow-ups. Those treated with FIT experienced large reductions in weight and waist circumference. Relative to both the MI group and baseline, participants treated with FIT continued to lose weight after treatment ended.

[insert figure 2]

Our primary statistical models estimated the differences between-groups, conditional on baseline BMI, at month 6 and 12; results are presented in Table 2. We found substantial and statistically significant differences between the MI and FIT groups at both follow-ups.

To make probability statements about the size of benefit obtained by participants undergoing FIT, we re-estimated our mixed models using a Bayesian procedure. Table 2 shows treatment effects, and associated 95% credible intervals from these models.

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[insert table 2]

For weight and waist circumference, there was overwhelming evidence that FIT was beneficial. Similarly, for GQOL the difference between groups at month 6 was statistically significant. In the FIT group, 58/59 participants would recommend the intervention to others: one might recommend. In MI, 53/55 would recommend, 2 might.

To help clinicians and others evaluate the likely benefit of FIT in clinical practice, we computed the posterior-probability that the benefit of FIT for a new participant would exceed a range of values between 0 and 15kg lost, and between 0-15cm of waist reduction (Figure 3): [insert figure 3]

When considering the risks or benefits of interventions, clinicians, participants and researchers benefit from probability information presented as 'natural frequencies' or in 'pictographs' (51). Consequently, we used the same model-based simulations to calculate the range of likely prognoses from the participants' perspective (Figure 4). After treatment, only 22% of MI participants were predicted to lose 5% or more of their initial weight, compared with the NICE target (52) that 30% do; after 12 months this figure was 23%. In contrast, 54% of new FIT participants were predicted to lose at least 5% of their initial weight after treatment, and 75% are predicted to lose this much by 12-months. Stated differently, nine of every 10 participants would have benefitted more from FIT than from MI (probability FIT>MI for kg lost at 12m = 0.94; for cm lost it is 0.85); for half of these participants, the expected additional benefit is substantial (> 5kg difference in projected outcomes, see data supplement).

[insert figure 4]

Economic assessment:

We based our inputs to the PHE assessment tool (50) on the conservative assumption that MI was equivalent to no-treatment, and that FIT participants would begin to gain weight immediately after the 12-month follow-up. We modelled costs on the basis that 58 new patients would be treated with FIT and that they would reduce their BMI by an average of 2.148 kg/m² over 1 year (based on our primary outcome models). We very conservatively assumed that each hour of individual treatment would cost £250 to deliver, and entered a worst-case per-participant cost for FIT at £1000.

Even based on these highly conservative assumptions, the PHE model suggests that FIT would be cost-effective from the healthcare perspective within three years, judged by NICE's conventional willingness-to-pay threshold of between £20,000 and £30,000 per QALY. Cost-per-QALY after three years was £22,036, falling to £12,363 after five years, and £7,229 after 10 years. Including costs of social care and the prospect of increased employment, cost per QALY was only £12,968 after three years, £3,739 after 5 years, and was cost-saving from a 10-year perspective.

Discussion

In this first randomised controlled trial of FIT, we have shown that two FIT interviews and nine brief booster phone calls, amounting to under 4 hours of therapist contact over six months, resulted in substantially greater and clinically meaningful weight loss and waistline reductions at six months, compared with MI. Participants in the FIT arm, but not MI, continued to lose weight and waist circumference in the unsupported 6-month maintenance phase. Participants in both treatment groups reported improved quality of life at 6 months, but FIT participants reported greater improvements. Seventy-one percent of the FIT group lost more than 5% of their initial weight, easily exceeding the NICE weight management target that at least 30% of service-users should do so (52). MI did not meet the NICE target, with only 23% losing 5%.

Importantly, we found that FIT was acceptable to participants and that they would recommend FIT to a family member, friend or colleague. Because the delivery of FIT closely matches the protocol of an existing intervention (MI), scaling delivery to larger numbers of participants should be straightforward, with existing MI practitioners requiring only minimal additional training.

To put these findings into a broader context, FIT performed favourably compared to a longer, more intensive intervention in a recent UK trial: Ahern and colleagues (53) tested weight loss in participants with overweight and obesity referred by GPs to Weight Watchers. Participants randomised to the Weight Watchers programme for 12 months had lost an average of 6.8kg at 12 months, only 0.4 kg more than participants in our RCT, who received less than 4 hours of FIT spread over 6 months. Participants on the standard 12-week Weight Watchers programme lost less than FIT participants in this study: only 4.8kg on average (53).

The approach tested in this trial, of providing solely motivational support, differs from the strategy recommended by Public Health England (54,55) of combining behaviour change techniques with lifestyle education and advice. NICE recommends including MI and imagery in behaviour change strategies. FIT combines both in a coherent, structured intervention that trains users to become their own therapist; the present results support this approach. It remains to be determined if combining FIT with diet and physical activity education would generate superior outcomes.

Sustained reductions of around 5% of body weight can effect significant health improvements, such as decreased blood lipids, precursors of Type 2 diabetes and improved blood pressure (3,4). Weight loss of between 5% and 10% is associated with significant improvements in cardiovascular disease risk factors (5). The reduction in waist circumference, from an average of 106 cm to 97 cm by 12 months in FIT, brings its own health risk reductions: excess abdominal fat indicated by a high waist circumference in men (>102 cm), presents a fivefold increase in the risk of developing diabetes (9). For women, across a range of baseline BMIs between 25-50 kg/m², waist reduction of 5-10cm is associated with a reduction in cholesterol and systolic blood pressure (56). Results from the Public Health England economic assessment tool suggest that these health benefits would make delivery of FIT cost effective, although detailed cost-effectiveness evaluation must form part of additional large-scale evaluations of FIT.

The fact that FIT outperformed the best established motivational intervention by such a margin is encouraging. We demonstrated a mean weight difference of 2kg for FIT, compared with the active MI intervention group at 6 months. This benefit of FIT over MI was larger than the benefit of MI over minimal control interventions in Armstrong et al's., (24) meta-analysis of MI for weight loss: mean difference = 1.47 kg 95% CI = -2.05 to -0.88 ataround 6 months. However, we note that weight in the MI group stabilised after six months, and successfully preventing weight gain is an important health focus (57,58). That FIT demonstrates such an improvement over an existing treatment, and produces continued weight loss after the end of the intervention period, highlights the benefit of developing and adapting existing interventions based on recent developments in cognitive science.

Limitations and future directions

We focused purely on motivation, providing no lifestyle advice or information. We did not assess participants' knowledge of nutrition or physical activity. First, this was in keeping with the autonomous spirit of MI which FIT retains. The ethos of both interventions is to motivate participants to seek the information or support they need to achieve their goals. Second, we focused on process outcomes in this trial, rather than content outcomes. Assessing previous knowledge at baseline could have led participants to believe they should discuss their knowledge, or to expect advice or prescribed diet and exercise plans. Although we recruited from the general public, we acknowledge that we may have attracted a wellinformed sample (e.g., the kind of person who would sign up for a study conducted at a university). Perhaps this sample was more knowledgeable than a random sample of people with overweight, but this certainly did not make them more successful; they still struggled with overweight or obesity when they signed up for the study. There is little evidence that knowledge alone motivates behaviour. For example, a recent, large cross-sectional study on self-management of glycemic control found no correlation between knowledge about type 2 diabetes and actual self-management behaviours (59). Even with healthcare professionals, education did not lead to behaviour change. McCluskey and Lovarini, (2005) tested an educational intervention to improve evidence-based practise amongst allied health professionals. Improved knowledge was maintained at 8 month follow-up but behaviour change was very limited, with nearly two thirds of health professionals still not reading any research literature. It is conceivable however that education is beneficial in populations with very limited knowledge of nutrition and exercise. Future studies should therefore assess whether FIT works best as an alternative to established weight-loss programmes based on lifestyle education and advice, or as an adjunct to them.

As far as possible, we matched MI and FIT for intervention intensity. There were the same number of sessions, scheduled for the same duration, in both conditions. Although the dialogue for FIT incorporated the same essential components as for MI, we added some extra elements to the MI manual to add depth to the interview and equate the time taken. In FIT, all participants were offered the Goal in Mind app to guide their imagery practice. In MI, all participants were given goal sheets to review at home. If anything, MI participants had more time to talk to the therapist because they did not do imagery exercises.

FIT achieved larger effect sizes than expected. Because of practical constraints on recruitment, our sample was smaller than that recommended by our power calculations to detect modest to moderate effect sizes, therefore it is plausible that our trial over-estimates the true effect of FIT, i.e. a 'Type M' (magnitude) Error (61). Nonetheless, the posterior probability for an effect of FIT < 1kg lost was extremely low, and the evidence that FIT was preferable to MI was substantial.

This was the first efficacy trial of FIT for weight loss, and our results must be replicated in a larger multi-centre trial to be confident that FIT can be delivered effectively at scale by other therapists. However, we have achieved proof of concept, and compared the intervention with a well-established intervention for weight loss. Although the FIT group maintained their weight loss at our 12- month follow-up, further trials should follow participants for several years to ensure that FIT does indeed help participants maintain the weight loss achieved during treatment, and to properly assess the health economic benefit of these reductions.

Conclusion:

Less than 4 hours of Functional Imagery Training, a novel intervention that combines motivational interviewing with mental imagery training, led to substantially greater weight loss over 6 months than MI alone, despite the fact that specific education on lifestyle and activity was absent from this intervention. The benefits of FIT persisted to 12 months; participants continued to make substantial reductions in weight even after therapy ended.

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Table 1. Baseline demographics, split by intervention:

	MI (Range,		FIT (Range,			
	Median, Mean)		Median, Mean)			
N	55		59			
Gender (N)	Female	40	Female	43		
	Male	15	Male	16		
Age (N years)	Range	19-70	Range	20-72		
	Median	43	Median	45		
	Mean	42	Mean	45		
BMI (kg/m²)	Range:	24.51-53.33	Range	25.98-47.97		
	Median	31.34	Median	31.85		
	Mean	32.54	Mean	33.21		
Weight (kg)	Range	131-59	Range	62.30-140.5		
0 (0)	Median	87.40	Median	89.40		
	Mean	89.66	Mean	91.46		
Waistline (cm)	Range	80-148	Range	79-144		
, ,	Median	105	Median	103		
	Mean	106.01	Mean	106.78		
Employment status	Employed full-time	12	Employed full-time	20		
(N)	Employed part- time	18	Employed part- time	14		
	Retired	5	Retired	6		
	In education	4	In education	7		
	Unemployed	3	Unemployed	5		
	Other	11	Other	4		
	Self-employed	1	Self-employed	2		
Highest level of	GCSE	15	GCSE	14		
education (N)	NVQ/Diploma	4	NVQ/Diploma	5		
	Trade	8	Trade	6		
	A or O-Levels	14	A or O-Levels	15		
	Access course	2	Access course	4		
	Foundation degree	2	Foundation degree	1		
	Degree		Degree	2		
	Postgraduate	4	Postgraduate	3		
	Degree	1	Degree	4 -1		
	No info given	4	No info given	5 ¹		

¹ There were no statistically significant differences between groups at baseline

Table 2. Between group contrasts (with Satterthwaite corrected degrees of freedom for Kg and Cm) and posterior mean differences (and 95% credible intervals) for the effect of FIT vs. MI at month 6 and 12. MCMC = Markov Chain Monte Carlo estimates from Bayesian model fits.

		FIT		MI					Treatme		
Outco	Follow	(mea	FIT	(mea	MI				nt effect	low	upp
me	up	n)	(sd)	n)	(sd)	df	t	р	(MCMC)	er	er
Cm	Baseli	106.0	13.7	105.5	12.5						
	ne	7	5	0	1						
Cm	Mont	99.05	12.6	102.7	13.3	205.	-	<	-4.444	-	-
	h 6		1	8	7	4	4.72	.00		6.32	2.56
							7	1		8	0
Cm	Mont	96.97	12.5	103.0	12.4	206.	-	<	-6.697	-	-
	h 12		9	4	5	1	7.01	.00		8.60	4.80
							2	1		2	1
Kg	Baseli	90.48	15.9	89.13	14.7						
_	ne		0		6						
Kg	Mont	86.37	15.0	88.39	15.7	161.	-	<	-3.670	-	_
_	h 6		7		2	5	4.87	.00		5.20	2.13
							7	1		3	9
Kg	Mont	84.04	15.9	88.46	15.3	163.	-	<	-5.929	-	-
J	h 12		6		4	4	7.70	.00		7.48	4.41
							7	1		2	8
GQOL	Baseli	62.13	10.5	61.71	14.5						
	ne	, .	9	y = -	1						
GQOL	Mont	75.81	11.6	72.53	10.4	109.	2.10	.03	2.831	0.09	5.56
	h 6		6		2	0	7	7		1	5

^{2,3}

² Cm=waist circumference in cm, kg=mean weight in kg, GQOL=mean score of Global Quality of Life assessment

³ Footnote: MCMC: Markov Chain Monte Carlo estimates from Bayesian model fits.

Figure 1. CONSORT Flow Diagram

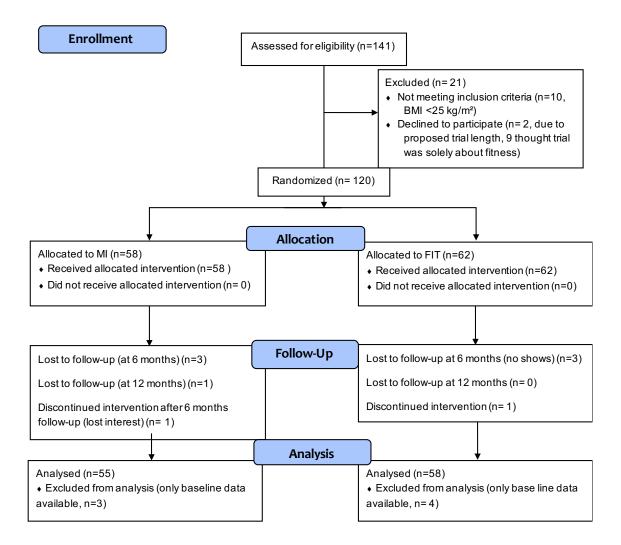


Figure 2. Mean waist circumference and weight with 95% confidence interval, by group.

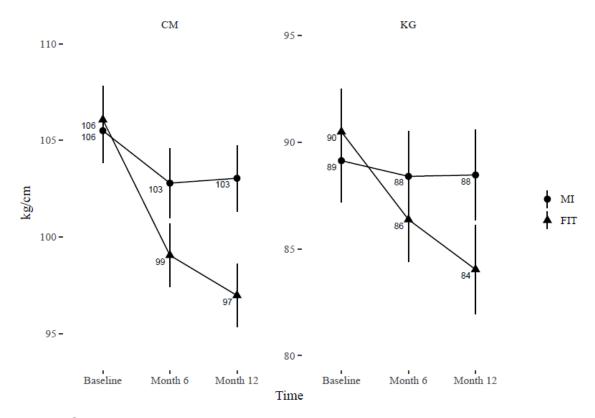


Figure \mathfrak{P} : Unadjusted weight and waist circumference by group: mean and 95% confidence interval.

Figure 3. Prognosis for new participants randomised to FIT vs. MI, expressed as the probability the benefit will equal or exceed the value on the x-axis.

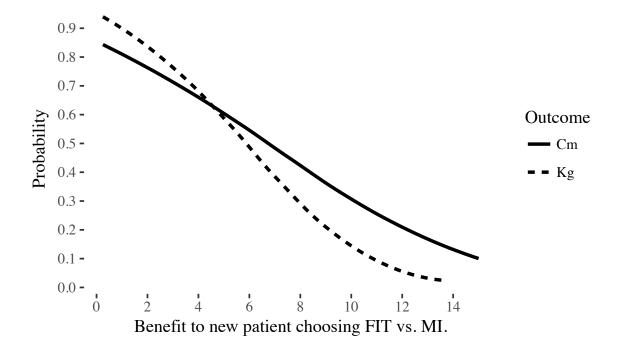


Figure 4. 12 month prognosis for 100 new participants undergoing MI or FIT.

