An app-, web- and social support-based weight loss intervention for adults with obesity: the HelpMeDoIt! feasibility RCT

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Scientific summary

The HelpMeDoIt! feasibility RCT

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Scientific summary

Background

Obesity is one of the top 10 risk factors for burden of disease worldwide. Preventative interventions which are accessible and engaging are necessary to reverse current trends. Advances in technology offer opportunities for engaging people with health behaviour change. Most adults in the UK, including those in socially disadvantaged groups, own a smartphone. Social support, particularly from existing social resources, has an important role in successful weight loss and maintenance and there is strong evidence for goal-setting and self-monitoring as successful behaviour change techniques. Combining social support with known behaviour change techniques, using accessible and engaging technology, has the potential to impact behaviour change at a population level for low cost. If brief engagement with an application (app) could catalyse input from existing social connections to support longer-term change, then this could offer a sustainable approach. The HelpMeDoIt! study aims to explore the feasibility and acceptability of a weight loss intervention delivered via smartphone app and website, incorporating goal-setting, self-monitoring and social support from existing social networks.

Objectives

1. To develop an app- and web-based intervention that enables participants to set and monitor goals and facilitates effective social support.
2. To investigate recruitment and retention as well as feasibility and acceptability of the intervention.
3. To explore the potential of the intervention to reach traditionally 'hard to reach' groups (e.g. those in lower socioeconomic groups).
4. To explore the barriers to and facilitators of implementing the intervention.
5. To assess the feasibility and acceptability of outcome measures for diet and physical activity in this population.
6. To use outcome data (diet, physical activity, BMI) to help decide on a primary outcome and to estimate the potential effect size of the intervention to facilitate the calculation of an appropriate sample size for a full trial.
7. To assess data collection tools and obtain estimates of key cost drivers to inform the design of a future cost-effectiveness analysis.
8. To investigate how participants and helpers engage with goal-setting, monitoring and social support using new technologies and how these elements interact within a behaviour change intervention.
9. To develop a conceptual model of how the key mechanisms of goal-setting, monitoring by self and others, social support and behaviour change are facilitated by the intervention.
10. To test the logic model and theoretical basis of the intervention.
11. To explore the characteristics of participants' social networks and the influence social networks have on participant experiences and outcomes of the intervention.
12. To assess whether or not an effectiveness trial is warranted.

Methods

HelpMeDoIt! was completed in two stages. In stage 1 we developed and piloted the intervention. User involvement was central to the iterative development process, with recruitment of both a panel of user representatives ($n = 10$) and a user testing group ($n = 28$). In this stage we explored (1) how to promote engagement with the app and website and their success in encouraging realistic goal-setting and self-monitoring; (2) the acceptability and functionality of the social support content; and (3) the views of users

on how the intervention might attract and support helpers. The resulting intervention and programme theory were developed using intervention development frameworks, focus groups, think-aloud interviews and a 3-month testing phase of the prototype app and website. The focus groups were audio-recorded and analysed using a thematic approach. Feedback from the think-aloud interviews informed further refinement of the app and website.

Stage 2 was a feasibility trial, with process and health economic analysis, that aimed to examine feasibility, acceptability and trial parameters for a future trial. Participants were eligible if they had a body mass index (BMI) of $\geq$ 30 kg/m^2, owned a smartphone and were interested in losing weight. Participants were randomised in a 2 : 1 ratio to the intervention or the control group. The intervention group were given access to the HelpMeDoIt! app and website for 12 months. The website provided evidence-based information on weight loss, setting and monitoring goals, as well as harnessing social support from family and/or friends. The app allowed participants to (1) set goals for weight loss, (2) monitor progress and (3) invite one or more helpers from their existing social network. Helpers who agreed to provide support were also able to access the website and app, and see participants' goals and progress. They could provide support to the participant via the app and also outside the app (e.g. face to face, telephone call). The control group received a leaflet on healthy lifestyle and were offered access to the app and website after follow-up was complete.

The key outcome of the study was whether prespecified progression criteria were met in order to progress to a definitive trial. Data were collected at baseline and 12 months and focused on exploring the feasibility and acceptability of the intervention and evaluation methods. They included (1) quantitative outcomes assessing three primary outcomes (BMI, physical activity and diet); (2) secondary outcomes of weight, waist and hip circumference, social support, self-efficacy, motivation, mental health and health-related quality of life; (3) qualitative interviews with a subsample of participants and helpers at 6 and 12 months; (4) health economic outcomes of NHS resource use, participant-borne costs and intervention costs; and (5) a process evaluation exploring the programme theory and logic model, contextual factors, fidelity, exposure, reach, recruitment, retention and contamination. Statistical analyses focused on the feasibility outcomes, assessing which of the potential primary outcomes was most feasible by assessing data completeness and potential sensitivity of the measure for detecting change, as well as providing preliminary estimates of intervention effects. The health economics data were summarised and described using mean values and variation around these estimates. The key fixed and variable costs of developing the intervention were described and summarised. The qualitative interviews were analysed thematically as part of the process evaluation.

Results

The stage 1 development work produced (1) a website that provided evidence-based information for lifestyle change and harnessing social support; and (2) an app that facilitated goal-setting, self-monitoring and supportive interaction between participants and their helper(s). In stage 2, prespecified progression criteria were achieved. It was feasible to recruit and retain participants in the trial (progression criteria 1–3). We developed an intervention that was feasible to deliver and acceptable to helpers and participants (progression criterion 4). Two-thirds of intervention participants (including those who withdrew from the study) visited the app twice or more (progression criterion 5). Data collection methods were feasible to use, with the exception of the 24-hour multiple pass recall dietary measure and issues with obtaining valid accelerometry data (progression criterion 7). Barriers and challenges to implementation have been planned for and are surmountable (progression criterion 6).

A sample of 109 participants were recruited to the HelpMeDoIt! trial and randomised 2 : 1 to the intervention (n = 73) or control group (n = 36). At baseline, 69.7% (n = 73) of participants were women; the mean age was 47 years (range 25–68 years); the mean BMI was 37.6 kg/m^2; and over one-third were from the highest quintile of socioeconomic deprivation. At 12 months we achieved a follow-up rate of 77.1% (84 out of 109 participants). Follow-up rates were different between the intervention and control groups (71% and 89%, respectively).

Exploratory outcomes

The feasibility trial was powered not to detect statistically significant changes, but to explore the feasibility and sensitivity of measures for use in a definitive trial. Three outcomes were assessed: BMI, physical activity and diet. BMI was successfully measured in 98% of the sample (82% objectively and 16% via self-report) and diet (Dietary Instrument for Nutrition Education questionnaire) was measured in 96% (81 out of 84). Physical activity data were successfully collected via (1) self-report 7-day physical activity recall from 96% of participants; and (2) objective accelerometry from 46% of participants. The secondary outcomes were feasible and acceptable to use.

Objective physical activity data showed moderate to large effect size estimates across several measures, particularly the daily step count and sedentary time. These findings were amplified in per-protocol analyses, and appeared strongest in those with lower levels of physical activity at baseline. There was no evidence to suggest that self-report physical activity was different between those who did and those who did not provide valid accelerometry data, thereby increasing confidence in these results. However, these outcomes were poorly completed, and these findings were sensitive to missing data. Overall for the key weight-related outcomes of interest, the confidence intervals were generally wide and, therefore, consistent with clinically relevant benefits. Most effect size estimates had confidence intervals that included 0.5 in favour of the intervention, which would generally be considered a moderate effect size. Given the low cost of interventions of this type, a small population-level effect size may be enough for an intervention to be cost-effective.

Health economics outcomes

Findings showed that questionnaires designed for measuring resource use would be suitable for inclusion in a full study. The cost per participant for intervention delivery was high, at £740; however, these costs included the upfront cost of developing the intervention. In a future trial, the cost per participant would be lower, mostly covering hosting and software support.

Process evaluation: qualitative findings

Interviews were conducted with 35 individuals (22 participants and nine helpers at 6 months and an additional four participants at 12 months). Overall, findings showed the HelpMeDoIt! intervention to be both feasible and acceptable. Participants were also positive about the evaluation methods, such as the data collection measures and retention strategies, and there was no evidence of contamination in the data.

Insights from participants

Although there were initial technical problems with the app, the majority of participants interviewed were positive and engaged with HelpMeDoIt!, leading them to engage social support either via or outside the app. The main changes made by participants were small improvements to diet and/or physical activity, and these were often associated with other actions, such as joining a slimming club or gym. Some participants reported weight loss but also experienced difficulty maintaining their weight loss.

Social support was a key element, with helpers providing emotional, informational and instrumental support to participants. Helpers reported that they received mutual support with their own lifestyle goals. Many participants set goals via the app for healthy eating, physical activity and other behaviours. Participants reported monitoring their progress towards goals and also using other apps for self-monitoring. Motivation was identified as a key mediator influencing behaviour; encouragement from the helpers was important in this regard.

Insights from helpers

Helpers described how they enjoyed supporting their friend with their weight loss goals. Few helpers used the app because they experienced technical difficulties, lacked confidence with smartphones or preferred to support their friend outside the app. They believed that their support contributed to their friend's motivation to make healthy changes. Many helpers found that they were also more motivated to eat well and be active themselves because of their role.

Process evaluation: other findings

Contextual factors were reported as influencing participants' engagement with the intervention. These included significant life changes, personality traits, mood and social norms. Various contextual factors were highlighted for consideration in future work, including difficulty asking friends/relatives for support; lack of available support; social and group norms; and personal barriers to lifestyle change, such as motivation.

Despite a 3-month testing phase, there were initial technical issues with the app. The majority of the reasons for dissatisfaction and barriers to use were related to these technical issues. The app underwent a 'rebuild' that resolved the software problems. Participants who used the app most frequently, once the technical issues were resolved, provided the most positive feedback via both qualitative and quantitative measures.

Of the 54 (74%) participants who downloaded the app, 48 (89%) used it twice or more. Greater engagement with the app was positively correlated with objectively measured physical activity, improved diet and reductions in BMI. Although identified associations could indicate mediating effects, they could also be a result of reverse causality or artefacts of another predictor of success. Of the 954 goals created by participants, 61% were completed. Most helpers did not engage with the app on a frequent basis. Qualitative findings suggested that helpers were uncertain about how to help the participant using the app, with many providing support outside the app (e.g. through face-to-face interactions). Engagement with the website, by both participants and helpers, was low, suggesting a need for either (1) better signposting or (2) alternative methods of accessing information, for example an encyclopaedia function within the app.

The qualitative findings from stage 1 helped refine the initial programme theory. Social support, motivation, goal-setting and self-monitoring were supported by the stage 2 qualitative data as key mechanisms. Multiple contextual factors were also identified, which could have a negative or positive impact on the intervention. Insights were gathered on the participant–helper relationship, and participants reported positive lifestyle changes in both their helpers and their broader social network. The resulting programme theory and logic model were refined to reflect these findings.

Conclusions

The trial methods and intervention were feasible and acceptable. Suitable outcome measures were identified to assess future effectiveness and cost-effectiveness. Social support from existing social networks, motivation, goal-setting and self-monitoring were supported as core elements of the programme theory. Social support was key and the app was a catalyst to engaging this support either via the app or outside the app. The study had a few key limitations, including technical issues with the app early on and low engagement of helpers with the app. The study could have benefited from greater helper input during the development stage, and ethical constraints prevented us from contacting helpers directly to ask them to take part in an interview. A number of key learnings from the feasibility trial could inform a future definitive evaluation in terms of intervention refinement (e.g. functionality of the app to enhance engagement), but also in terms of the evaluation methods.

Implications for health care

This was a feasibility study. However, if effectiveness was demonstrated in a full trial there are several potential implications, including:

- HelpMeDoIt! may have the potential to deliver a low-cost, high-reach intervention for adults with obesity.
- HelpMeDoIt! could be used as a complementary intervention used alongside other health-care or lifestyle services.
- HelpMeDoIt! may have the potential to positively influence the lifestyle of individuals in a participant's broader social network.
- This approach to mobilising social support for health behaviour change could be used for other lifestyle behaviours.

Recommendations for research

- To further understand the motivation and engagement of helpers in providing social support to participants.
- To assess the effectiveness and cost-effectiveness of the HelpMeDoIt! intervention after further refinement of the intervention.
- To further explore the key mechanisms of change identified by the HelpMeDoIt! feasibility findings.

Trial registration

This trial is registered as ISRCTN85615983.

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