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Title: A text-messaging and pedometer program to promote physical activity in people at high risk of type 2 diabetes: A development and feasibility study for the PROPELS Trial

Abstract

Background: Mobile technologies for health (mHealth) represent a promising strategy for reducing type 2 diabetes (T2DM) risk. The PROPELS trial investigates whether structured group-based education alone or supplemented with a follow-on support programme combining self-monitoring with pedometers and tailored text-messaging is effective in promoting and maintaining physical activity (PA) among people at high risk of T2DM.

Objective: This paper describes the iterative development of the PROPELS follow-on support programme and presents evidence on its acceptability and feasibility.

Methods: We used a modified mHealth development framework with four phases: 1) conceptualisation of the follow-on support programme using theory and evidence; 2) formative research including focus groups (participants: n=15, aged 39-79 years); 3) pre-testing focus groups using a think aloud protocol (participants: n= 20, aged 52-78 years); and 4) piloting (participants: n= 11). Analysis was informed by the constant comparative approach, with findings from each phase informing subsequent phases.

Results: The first three phases informed the structure, nature and content of the follow-on support programme, including the frequency of text-messages; the need for tailored content and two-way interaction; the importance of motivational messages based on encouragement and reinforcement of affective benefits (e.g., enjoyment), with minimal messages about weight and T2DM risk; and the need for appropriate language. The refined programme is personalised and tailored to the individual's perceived confidence, previous activity levels and PA goals. The pilot phase indicated that the programme appeared to fit well with everyday routines and was easy to use, also by older adults.

Conclusions: We developed a feasible and innovative text-messaging and pedometer programme based on evidence and behaviour change theory and grounded in the experiences, views and needs of people at high diabetes risk. A large scale trial is testing the effectiveness of this four-year programme over and above structured group education alone.

Trial registration: ISRCTN83465245

Keywords: Physical activity, mHealth, text-messaging, pedometer, tailoring, type 2 diabetes, intervention development

Introduction

Like most developed countries, the UK is facing a growing prevalence of type 2 diabetes (T2DM) [1]. Furthermore, in England there has been a marked increase in the number of people identified with impaired glucose regulation (IGR): blood glucose levels higher than normal, but below the threshold for T2DM and associated with increased risk of developing T2DM and further complications [2]. Given the significant economic burden of treating T2DM [3], prevention of the condition is a public health priority.

The main targets for T2DM prevention are weight loss and physical activity (PA) promotion [4,5]. PA slows the progression of T2DM and its cardiovascular consequences [6], and thus is often argued to be a cornerstone of T2DM prevention initiatives [5]. Indeed, several large, high quality clinical trials have shown that relatively modest changes in lifestyle (e.g., increased PA) can reduce its incidence [7,8].

Structured self-management education is recommended for facilitating lifestyle change (including PA) among people with T2DM and those identified as being at high risk of developing T2DM [9]. The Pre-diabetes risk Education and Physical activity Recommendation and Encouragement (PREPARE) study, which combined group-based structured education and pedometer use, reported improvements in glucose regulation in people at high risk of T2DM [10]. Notably, only the group that received a pedometer in addition to structured education demonstrated better clinical outcomes. Indeed, meta-analyses have shown that interventions that prompt self-monitoring by pedometers resulted in increased PA [11,12]; among individuals with T2DM, walking programmes that do this have shown that they are feasible and effective at increasing moderate intensity bouts of PA [13][14].

T2DM prevention guidelines recommend the provision of *ongoing* support for people identified as being at risk, particularly when barriers for behaviour change are encountered [9,15]. Although primary care offers a system for identifying individuals at high risk of T2DM (e.g., through the NHS Health Checks in England), it lacks the capacity and resources to offer ongoing support through regular face-to-face contact with healthcare professionals. As such, there is a need to develop and evaluate scalable and cost-effective T2DM prevention programmes that provide ongoing behaviour change support beyond structured education and pedometers, and are suitable for implementation in routine care [16]. Tailored, computer-generated feedback on pedometer-measured step counts may be a cost-effective means to provide ongoing support for PA among people at high risk for T2DM. One way of achieving this is through the use of mHealth (i.e. mobile phone technology [17]), specifically via short message service (SMS), hereafter referred to as ‘text-messaging’.

mHealth approaches

While smartphone ownership is increasing (estimated at 55% in the UK adult population), it is less than 20% in people aged over 65 years – who are more likely to be at risk of T2DM [18]. Non-smart mobile phone ownership is commonplace in this age group, estimated at 77% in 65-74-year olds [19], hence text-messaging currently has a potentially wider reach in this group. Furthermore, text-messaging can be automated, individually tailored, and allows frequent delivery with asynchronous receipt (i.e. people can choose when to read the messages). Thus it is potentially an efficient delivery

channel for providing participants with information, feedback and a choice of when to access messages.

Text-messaging interventions are increasingly used in T2DM prevention. A recent randomised controlled trial (RCT) [20] evaluated a text-messaging T2DM prevention intervention delivering randomly generated 'lifestyle advice' messages to men (aged 35-55) in India. It reported significantly lowered incidence of T2DM at 24-month follow up. However, no between-group differences in self-reported PA were observed. A T2DM prevention intervention in a general population (mean age of 42 years) [21,22], that sent very frequent (5-7 per week) tailored messages (including general educational messages, diet and exercise tips and health reminders) and prompt messages to encourage goal setting. It increased participants' risk awareness and knowledge of T2DM. However, the majority of text-messaging interventions for T2DM self-management and prevention have targeted clinical outcomes only, in younger and middle-aged adults (<55 years), and have not measured behavioural outcomes (e.g., PA)[23].

It is widely accepted that the development of complex behaviour change interventions, including mHealth approaches, should be informed by behaviour change theory, evidence and formative research [24, 25] and that sufficient details of the final intervention are reported [26][27]. Yet, many published mHealth studies for PA promotion do not describe the structure, content or evidence base for the intervention in enough detail to allow replication. Taken together, there is uncertainty about the active ingredients, effectiveness, feasibility and acceptability of evidence-based mHealth to increase PA, in a population at risk of T2DM that includes older adults.

Context for the current study: Walking Away from Diabetes and the PROPELS trial

'Walking Away from Type 2 Diabetes' [28, 29] is an annual group-based structured education session, (hereafter referred to as 'Walking Away'). It is delivered to (up to) 10 individuals by two trained educators over 3 hours. It is designed to promote walking by targeting perceptions and knowledge about IGR and PA self-efficacy as well as promoting self-regulatory skills such as goal setting, self-monitoring and problem solving for relapse prevention. Participants receive a pedometer, but no additional contact with educators beyond the session, hence no feedback on individual progress.

PROPELS (ISRCTN83465245) is a multi-site RCT that aims to examine the long-term effectiveness of the Walking Away education with different levels of ongoing support (over 4 years) [30]. The RCT includes three arms: group 1 receives an informational advice leaflet; group 2 receives the leaflet, annual Walking Away sessions and a pedometer; and group 3 receives the leaflet, annual Walking away sessions, pedometer, plus a comprehensive 'follow-on support' programme using pedometer self-monitoring, tailored text-messaging and telephone calls.

Purpose

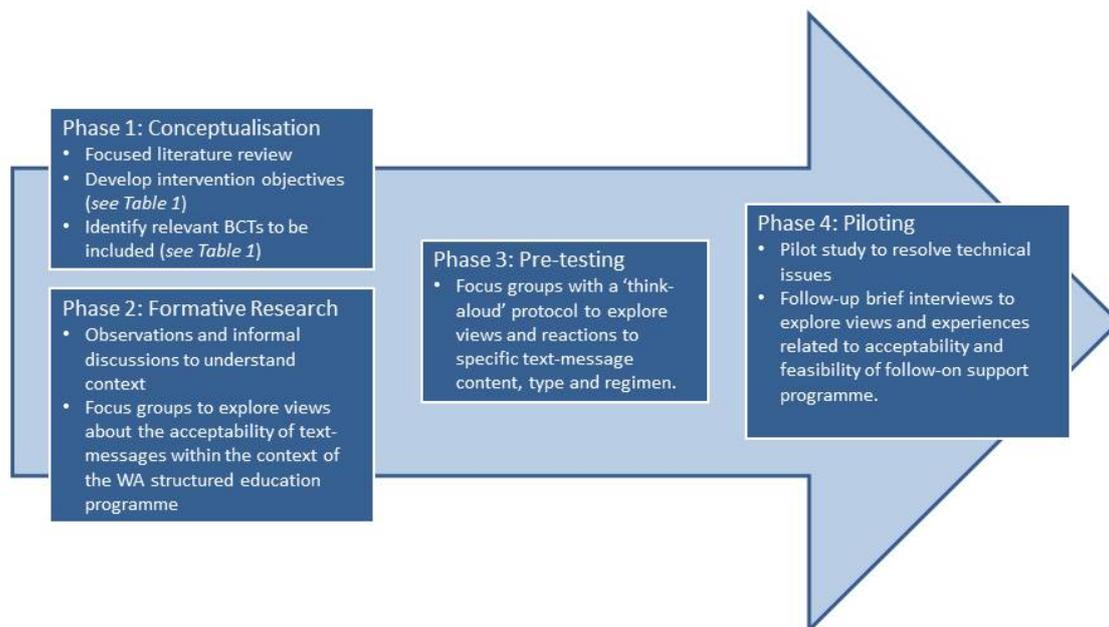
This paper describes the iterative development of the PROPELS 'follow-on support' programme and presents evidence about its feasibility and acceptability. The protocol for the PROPELS RCT is published elsewhere [30].

Methods

Design and framework

To develop the PROPELS follow-on support programme, we used a structured, iterative process involving concurrent and sequential research with the target population, while maintaining a strong focus on integration of theory and evidence. Our framework for intervention development and piloting was informed by Dijkstra and De Vries' [31] model for developing computer generated tailored interventions (to conceptualise the programme) and Whittaker et al.'s (2012) [32] mHealth development and evaluation framework, also drawing upon Fjeldsoe et al. (2012) [33]. An outline of our framework is shown in Figure 1. We describe the methods and results of each phase sequentially before presenting the finalised follow-on support programme. The development study was approved by NRES Committee East Midlands – Leicester (12/EM/0151) as part of the PROPELS RCT.

Figure 1: Design and framework of the PROPELS follow-on support programme



Methods and Results

Phase 1: Conceptualisation

We conducted a focused literature review to identify the key psychosocial determinants of increasing and/or maintaining PA levels among adults at risk of developing T2DM. We focused our review on text-messaging interventions to promote PA, but also reviewed PA behaviour change interventions within our target population more broadly (see sections below). In line with Dijkstra and De Vries' [31] model of developing computer generated tailored interventions, we then translated these determinants of PA into the key objectives (see Multimedia Appendix 1) of the PROPELS follow-on support programme.

Text-messaging for PA promotion

The evidence-base for text messaging interventions to promote health is growing, as demonstrated by two comprehensive meta-analyses. In one meta-analysis that focused on PA promotion using mobile devices [34], most of the included interventions delivered through text-messaging were passive, sending participants 'relay' messages (e.g., goal intentions) or generic, non-tailored information about health benefits, and participants were mostly younger adults. There were two exceptions: a pilot study with older people with chronic obstructive pulmonary disease [35] provided the control ('self-monitoring') group with a pedometer and mobile phone, prompted them to 'text' in details about their symptoms and exercise, and responded with a standard message to thank them and encourage continued submission of data. Intervention ('coaching') group participants received additional ongoing reinforcement 'coaching' messages. Objectively measured step count increased in the self-monitoring group only. The intervention was feasible to deliver; however, delivery was not automated as a nurse manually adjusted text responses, and scalability was limited due to all participants being provided with a phone. The second study – an RCT of a fully automated intervention consisting of a wrist-worn device, an interactive website to provide feedback on PA, plus text-messaging reminders of activity plans in middle aged healthy adults - reported significant increases in objectively measured activity compared to no support [36].

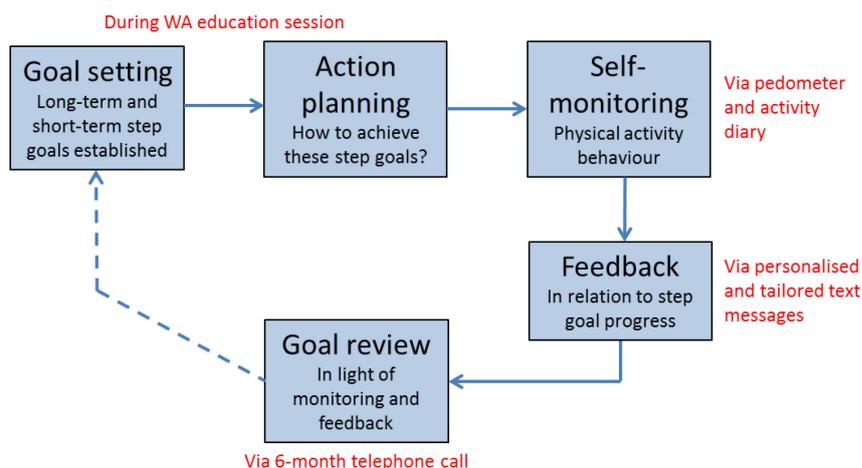
A second meta-analysis investigated the efficacy of different formats of text-messaging-based interventions for various health behaviour and outcomes. Message tailoring and personalisation were significantly associated with greater intervention efficacy [37]. Furthermore, interventions that involve decreasing frequency of messages over the course of the intervention were more effective than interventions that used a fixed message frequency [37]. Text-message-only PA interventions without tailored feedback did not increase PA (e.g., [38].) Hence, tailored feedback appears to be a promising component of mHealth PA interventions.

Taken together, PA interventions using text-messages may be more effective if they incorporate active components such as self-monitoring, provide tailored feedback and personalised messages, and decrease the frequency of text-messages over time.

Theory and Behaviour Change Techniques informing the PROPELS follow-on support programme

Health behaviour change interventions (i.e., not just text-messaging interventions) that combine self-monitoring with at least one other self-regulatory BCT (e.g., goal setting) have been shown to be significantly more effective at increasing PA than those that did not include these BCTs [39]. These BCTs are congruent with the process of self-regulation or more specifically ‘control’ theory [40], which proposes that setting goals, self-monitoring behaviour, receiving feedback and reviewing goals following feedback are central to behavioural self-management. The PROPELS follow-on support programme was thus structured around behavioural self-regulation (See Figure 2). This facilitated the selection and sequencing of the primary BCTs that are prevalent in the programme’s components [41]. Specifically, during the 1-week educator telephone call PA goals and an action plan were established (See Figure 4). The subsequent text-messaging component drew upon a selection of BCTs to (a) encourage self-monitoring of PA behaviour, (b) provide tailored feedback regarding PA progress, (in order to highlight the discrepancy between goals and current behaviour) and (c) review behavioural goals. A more detailed description of all the BCTs employed within the PROPELS follow-on support programme is shown in Multimedia Appendix 1.

Figure 2. Modified self-regulation ‘control’ theory which informed the PROPELS follow-on support programme.



Interventions among people with, or at-risk of T2DM that included a higher number of BCTs [42] and interventions with a higher number of BCTs and specific BCTs such as goal setting [43] have been associated with more weight loss. Furthermore, there is consistent evidence demonstrating the importance of several other key determinants of PA behaviour change across general populations as well as high-risk groups. These include attitudes towards PA [44], intrinsic motivation [45] and (maintenance) self-efficacy [46] – especially when this is targeted in conjunction with self-regulation [47]. With this in mind, the PROPELS follow-on support programme also targeted other determinants of PA behaviour change via the text-message component and employed additional BCTs to achieve the overall intervention objectives (See Multimedia Appendix 1). Given that uncertainty remains about the acceptability of the aforementioned BCTs when delivered by text-message, one aim of phases 2-4 was to explore the acceptability and feasibility of this approach with our target population.

Phase 2 - Formative Research

In parallel with phase 1, we (KM,HE) conducted informal observations of Walking Away sessions in diverse regions where it has been commissioned into routine care pathways for the prevention of T2DM. In addition, we (KM,HE,WH) engaged in discussions with Walking Away educators involved in an ongoing evaluation of Walking Away taking place within primary care [29]. In this phase we aimed to become familiar with the delivery of Walking Away; develop initial ideas about the PROPELS follow-on support structure and content; understand the cultural and ethnic diversity of our target population; explore educators' views about supplementing Walking Away with text-messaging and pedometer support; and inform the development of topic guides for subsequent focus groups.

Following this, we conducted three formative focus groups with our target population. Eligibility criteria included having attended the Walking Away session within the last 3 years as part of an ongoing evaluation in primary care [29], having provided consent to be contacted with regard to other research within the department, and ability to speak and understand spoken English. Potential participants were sent an information leaflet and opt-in reply slip. A researcher telephoned those who had expressed an interest in taking part to check willingness and arrange attendance at a focus group. Written informed consent was taken immediately before the focus groups. Fifteen participants (5 women, 10 men) aged between 39 and 76 years participated. A flexible topic guide was used that covered experiences of Walking Away (e.g., what was most and least helpful for increasing PA and what could be improved to facilitate sustained changes); use of mobile phones in everyday life; and integration of a text-messaging follow-on support programme into Walking Away.

Focus groups were audio-recorded and transcribed verbatim. Our analytical approach was based on the constant comparative method [48]. Specifically, KM familiarised herself with the data and identified initial codes. This involved organising the data into meaningful groups and identifying interesting aspects in the data that formed the basis of repeated patterns (themes) across the data set. Codes were assembled into an initial coding framework (KM,HE); this was used to code the complete dataset. NVivo (qualitative data indexing software, QSR International) was used to facilitate the analysis.

The key findings from phase 2 that influenced intervention development and subsequent phases are presented under two interlinked themes: acceptability of text-messaging for PA promotion, and requirements for the structure of the follow-on programme, including text-message content.

Acceptability of text-messaging for PA promotion

The majority of participants reported using mobile phones in daily life and being able and willing to use text-messages, even if they were not in the habit of doing so as a primary means of communication. Most agreed that text-messages could serve as a useful reminder to aid habit formation, and provide additional support following an education session.

"I think if texting had been in it [Walking Away trial] before it would have helped my motivation a lot." [FG3]

The potential ease of integrating a text-messaging programme into daily life was highlighted; participants reported that a positive feature was the freedom to choose when to read a message and whether to act on the information provided within it.

"Whereas texting is ideal. You can carry on with your normal day to day living but still get the motivation." [FG1-A]

"You don't have to listen to it, but it's an idea. You can read all these and just take from it what you want to don't you? That's what we do, gather the information and decide what you want to do from there." [FG3]

Another perceived benefit was the opportunity to receive immediate feedback. Many participants reported that a two-way interaction, especially the process of reporting weekly step counts and receiving subsequent feedback, would facilitate motivation and maintenance and could foster a sense of accountability - i.e. someone to 'report' to.

"It would be good knowing that we'd put the figures in at the end of the week, that you have received them and that you've looked at them and that you're interested in what we're doing." [FG2-A]

Positive views were not unanimous. Some participants felt that texting was "not for [their] generation" although this did not necessarily mean they were against it.

"Well, you know, I think it's just that I don't use it, you know, it's not that I don't like it." [FG1-B]

A small number of participants expressed a strong dislike of text-messages, reporting that they are intrusive and/or impersonal.

"No, I wouldn't [want to receive text-messages], I would find that intrusive. It's bad enough "have you been mis-sold PPI", "have you done this".....so you don't even look at your text-messages. If it's not from family I block the lot so no, I wouldn't want text-messages." [FG1-C]

Requirements for the PROPELS follow-on support programme

Monitoring and feedback were salient themes. When reflecting on experiences of Walking Away, the pedometer was generally reported as a useful monitoring tool that promoted awareness of activity levels.

"And it does encourage you because you think, I've hardly moved! I think it keeps it in your mind." [FG2]

Some participants reported that they were still using it to monitor their PA two to three years after Walking Away, but the majority reported a lack of continued engagement with the pedometer or activity diary following an initial period of active engagement.

"You get up at half six in the morning, you think I'll go and get a wash and you get changed, and then you go off to work and, 'Oh, I didn't put it on'....you start to forget about it." [FG2-C]

"Once I've got home I think, oh, I don't think I'll do any more, I sit on the computer or watch the telly, I need someone to push me out, get out the chair and go and do a walk." [FG3-C]

Closely tied to the notion of self-monitoring was the importance of feedback for facilitating behaviour change and maintenance. Participants commonly reflected that a

lack of contact between the annual Walking Away group education sessions had decreased their motivation to continue with the strategies discussed in the session (e.g., setting goals and wearing a pedometer). Several participants described how feedback on their goal setting and progress with increasing PA levels would have been useful.

“It would have been nice to have the results of that [PA measures] because we never knew about that.” [FG1-D]

The preferred content of the text-messages differed greatly according to individual preferences and characteristics. Some participants, especially those who described themselves as “*self-motivated*” and “*the sporty-type*” (e.g., someone who has been fairly active in the past) wanted very different messages from those who described themselves as sedentary and “*needing more of a push*”. Furthermore, several participants reported prominent mobility issues, such as osteoarthritis, which meant that content focusing *solely* on walking was not relevant to them. Hence, the idea of the follow-on support content being tailored to individual characteristics (see phase 3 for more detail) was appealing to participants.

Participants were adamant that text-messaging should supplement, rather than replace, face-to-face contact, especially in relation to strengthening motivation. Some suggested that telephone support, in addition to text-messages, could foster rapport between PROPELS educators and participants and provide additional support that cannot be communicated via a text-message, thus overcoming the perception that text-messages are impersonal.

“But, [if] you've got somebody there you can speak to...say, “right I'm having a problem, I've done such and such and I can't register me steps” or whatever, it's just about [the educator] saying “right, you should do this” or I'll get somebody to ring you back and tell you what to do, you can't do that on text can you?” [FG1-E]

Taken together, the phase 2 findings indicate the need for (a) two-way interaction (e.g., inputting of step counts and immediate feedback about PA progress), (b) timely reminders for self-monitoring of PA, (c) further consideration of how to overcome perceived barriers to using text-messaging (e.g., by providing participants with an overview of the benefits of text-messaging for follow-on support at the initial Walking Away session), (d) tailored and personalised text-message content (explored further in phase 3) and (e) additional telephone support to enhance rapport between educator and participant and to provide support beyond text-messages only (e.g., problem solving and in-depth social support).

Phase 3: Pretesting

We created exemplar text-messages based on the findings of phases 1 and 2, and conducted four further focus groups (n=20; aged 52-77). Eligibility was the same as in phase 2 but we also invited participants from the Walking Away study control group who had not previously attended the programme [29]; recruitment and consent procedures were identical to phase 2. Prior to attending a focus group, participants received a pedometer and activity diary through the post, and were encouraged to record the number of steps per day for one week. Participants were asked to bring along a mobile phone to the focus group.

As in phase 2, a topic guide covered experiences of Walking Away. Additionally, it explored experiences of wearing the pedometer and recording steps. During the focus group, participants were sent example text-messages (Figure 3) in order to provoke reactions *in situ* and generate “think-aloud” [49] reactions and discussions about different types of messages. Messages were categorised as: ‘reminder texts’: reminders to wear the pedometer and log daily steps; ‘prompting texts’: instructions to text in step counts; ‘feedback texts’: feedback about behaviour including social reward and positive reinforcement; ‘motivational texts’: messages using BCTs to strengthen motivation for PA e.g., habit formation, commitment, reframing PA beliefs; ‘information texts’: information about health consequences; and ‘problem solving texts’: received when a goal was not met and included a list of pre-defined barriers as response options (see Figure 3). Depending on a participant’s response to the latter, they were then sent a tailored ‘motivational’ or ‘information’ text. Data analyses followed the approach used in phase 2. The coding framework was further developed (from the phase 2 coding framework) in order to reflect the current phase of development.

Figure 3: Example text-messages used in Phase 3

Reminder text

The text provides a prompt to self-monitor and record their physical activity.

Hi Carol. This is a reminder to wear your pedometer every day from when you wake up until you go to bed and log your step count in your activity diary.

Prompting text

The text provides an instruction to text in step counts.

Hi Fiona. Please text in your WEEKLY step count by entering the number of steps you have achieved in total over the past 7 days.

Feedback text

The text provides verbal reward if there has been effort and/or progress in physical activity.

Hi Geoff! Well done for maintaining your weekly step total - we realise how tough this can be each week! You are making fantastic progress - keep it up :-)

Motivational text (Habit formation)

The text prompts repetition of physical activity in the same context so that the context elicits physical activity

Even if you're glued to your phone, you don't have to be glued to your seat! Make it a habit this week to talk and walk whenever possible :-)

Information text

The text provides information about the health related consequences of physical activity.

Remember that walking is the single most effective form of exercise to reduce your risk of type 2 diabetes - it even improves mood and relieves stress :-)

Problem solving text

The text asks participants about their barriers over the past week (if a goal is not met).

What barriers have you experienced last week? TEXT: 1 for ILL HEALTH/INJURY, 2 for ENERGY/MOTIVATION 3 for TIME, 4 for OTHER/NO barrier

We present key themes that emerged from phase 3 that informed the PROPELS follow-on support programme. We categorise the data into views about self-monitoring of PA, and text-message type, language and frequency.

Self-monitoring of PA

The majority of participants reported that self-monitoring their daily steps with the pedometer increased their motivation to be more active, due to increased awareness of their own activity.

"I found the pedometer really, really useful. I didn't wear it all the time, but once I wear it I make sure I do 10,000 steps. If I looked at it half way through the day and think I've only done 5,000 then I went out for a walk purposely just to get the figures up." [FG4]

Some participants found the pedometer de-motivating or "disheartening", especially those with mobility problems who felt that they could not engage in walking as their primary activity, therefore the step count was always low.

"I wish that it was not just dependent on the steps. Because we do all sorts of other things rather than just steps" [FG7]

For these individuals, the self-monitoring process should allow for other activities to be counted (e.g., swimming and gardening).

Text-message type, language and frequency

'Reminder texts'.

Several participants commented that establishing appropriate frequency of reminder texts was key to avoiding the intervention becoming "off-putting" and "like Big Brother, checking up on you", especially when people had developed a habit of wearing the pedometer. This suggested a reduction in reminders as the intervention progresses.

"If you've got something constantly...well, not constantly, but weekly reminding you to do something then you're still there doing it. And possibly if you're doing it for several weeks then you'll get actually used to wearing it and putting it on. It's like putting your clothes on. You put your socks on, put your pants on, 'oh I'll put my thing [pedometer] on.' It's all getting used to what you're doing, like with your lifestyle." [FG5]

'Prompting texts'.

Participants were generally happy with the idea that a text-message would prompt them to input their weekly step count, as this was considered a useful motivational tool.

"I suppose the very fact that we would be doing it [texting in step counts] we are creating a certain level of discipline which we didn't have before." [FG4]

'Feedback texts'.

The exemplar feedback messages for having achieved one's step goal (e.g., positive reinforcement) were well received, again fostering a sense of accountability.

"We are all school kids in a sense, in our heads, so if someone says you did well it's really encouraging"

We tested a variety of feedback messages for the event of not achieving one's step goal. The consensus was that these should be fairly light-hearted, positive and encouraging. Messages that emphasised a discrepancy between the person's current behaviour and goal were well received, as long as the texts also offered encouragement and support, for example, by including positive elements alongside more negative feedback.

"...you've got to put in, you know, the positive that eliminates some of the negativity out of the messages. So this one was 'thanks for the text, keep wearing your monitor and logging your steps, try to increase your activity to ensure...' - it's not quite positive enough." [FG4]

Indeed, several participants commented that humour could be used to provide feedback when not achieving a step goal.

"You can't castigate somebody but you can try and get some laugh out of it from some point of view, saying 'get off your bottom and go for a walk!'" [FG6]

However, participants also recognised that messages could be interpreted differently and the use of humour was risky, especially when participants were low in confidence.

*"if I read that and I was in the wrong mood I'd take that as you're telling me what to do, and I'd say 'b*****r off'"* [FG4]

'Motivational texts'.

The feedback on 'motivational' messages varied greatly. Overall, participants reported that the language and content of the 'motivational' messages was acceptable due to the gentle suggestive nature rather than *"being told you've got to do it"*. Some exemplar messages were perceived as a *"bit dated"* (e.g., recommendations to not use a remote control to change the TV channel) or *"irrelevant"* (e.g., tips about using stairs at home; *"but I live in a bungalow!"*). Participants preferred practical tips and suggestions for increasing activity over more 'motivational' suggestions (e.g., *"try writing down your barriers to activity this week"*). In one focus group participants suggested *"general"* supportive messages, not necessarily linked to PA or health.

"I know why I'm doing it [to reduce the chances of T2DM] so we don't need reminding of it all the time" [FG7]

'Information texts'.

The consensus was that messages focusing on 'health consequences' of inactivity were too prominent and that a focus on benefits other than weight and reduced risk of T2DM would be preferred.

"You could just say 'good morning, this is PROPELS, hope you have a nice day or whatever...just simple - it doesn't need to really say anything'" [FG6]

"...when you've got a weight problem like I've got, I don't need to be reminded - I'm doing my best!" [FG4]

'Problem solving texts'.

Some participants felt that the pre-defined response format was not appropriate for 'problem-solving'.

"It's like one of those 'PPI' messages [spam text-messages about reclaiming missold insurance] - I hate those!" [FG4]

However, others liked the idea that they could easily ‘text-in’ the reason why they had not achieved their goal. Participants generally liked the tailored and personalised texts that were triggered by responding to the problem solving texts e (e.g., the message “Take it easy this week - we hope that you feel better soon” as a response to selecting the ‘illness or injury’ response option).

Tailoring.

The concept of individually tailored text-messages was very well received, especially in relation to individual goal progress and/or achievement.

“You should get the one [text-message] that’s relevant to you. If you’re doing more [steps], if you’re achieving your target or doing more, you still get one, but it should be different” [FG4]

Participants advised that “different people need different support”, especially in terms of confidence and self-discipline in adhering to an activity plan. They suggested that messages should be “less direct” or less “pushy” if people are struggling to meet their goal and/or have mobility problems limiting the amount of walking that they could achieve.

Language and frequency.

We tested language variations within the messages. The general feedback was that the language needed to be “formal”, “friendly” and “polite”, with use of the participant’s name, but limited use of emoticons.

“I’m just warning you that it might be interpreted that you are shouting at us because in text language, capitals [letters] is shouting” [FG5]

“It makes it sound as though you’re talking at us, rather than a computer” [FG6]

Regarding the frequency of messages, participants responded that “less is more”. Overall, they perceived daily messages as too heavy-handed and potentially demotivating.

“...otherwise if you are going to get this [text-message] daily you’re going ‘oh another one’ and you get fed up with it” [FG6]

In sum, the phase 3 findings expanded the findings from the previous phases by (a) further emphasising the importance of personalising messages and tailoring messages according to key variables (e.g., previous levels of PA, mobility issues that limit PA, individuals’ confidence in increasing PA, and goal achievement/progress) , (b) shaping the content of the messages (e.g., the type of benefits to focus on within the ‘motivational’ messages), (c) informing the frequency of messages and sequencing of the follow-on support programme, and (d) highlighting the importance of including other activities (e.g., cycling or swimming) to maintain engagement of participants who did other activities than walking alone.

As a result of the findings from phases 2 and 3, we added a ‘Week 1 Educator telephone call’ (see Figure 4) – a brief telephone-administered assessment to the proposed programme, which elicits key information required to tailor subsequent text-messages. We also added a conversion chart to the activity diary, which would enable participants to convert other activities (for which they might not be wearing their pedometer or for

which they perceive a pedometer to not accurately assess) into 'steps' for texting in. For example, this chart includes descriptions of other activities (such as "swimming breaststroke moderate effort" and "cycling 10mph") and provides a conversion into a step count (that is based upon MET equivalents [50]) that can be added to the participant's total.

Phase 4 – Piloting

Using the findings of phases 1-3, KM drafted an initial set of text-messages and tailoring matrices. The tailoring matrices (for each week of the programme) specify the individual characteristics to which each message will be adapted to. An example of the tailoring matrix for weeks 1 and 4 of the follow-on support programme is shown in Multimedia Appendix 2. SS developed a computer program to automatically generate and send the text-messages (in line with the tailoring matrices) and to handle incoming messages. We subsequently tested the content and schedule of the text-messaging and pedometer programme (in part) and the delivery processes required, e.g. registering with the text-message system, gathering information for tailoring, receiving and replying to the messages. We also aimed to identify and resolve potential technical issues with the automated system.

Participants were 11 people (6 men and 5 women) from the phase 2 and 3 focus groups who had indicated interest, including participants who were less keen on the use of text-messages. This 8-week pilot study mimicked the proposed initial eight weeks of the PROPELS follow-on support programme. Participants were posted an instruction booklet with details of how to register and what to expect from the text messaging system, a pedometer and an activity diary. They were instructed to wear the pedometer and self-monitor steps using the activity diary for one week to determine a baseline number of steps which would inform their step goals for the next eight weeks. KM administered the brief telephone assessment to elicit each participant's short- and long-term step goals, an action plan for increasing PA, and information for the tailoring variables. Then, each week, participants received a reminder message to prompt them to submit their weekly step count via text-message. This triggered an automated tailored feedback message, with the content depending on goal progress. Participants also received tailored motivational messages if they did not make progress with step counts or text in a step count.

After the 8-week period, KM conducted brief, semi-structured telephone interviews with all available participants (n=10) in order to gain their feedback on the programme. Interviews were recorded, transcribed, and analysed as in phases 2 and 3.

We present findings on participants' feedback on the programme's content and structure, and technical issues.

Programme content and structure

Most participants found that the 'follow-on support' motivated them to be physically active, due to increased awareness of their own activity. Participants found the telephone call, in which the brief assessment was administered, helpful in providing additional support, especially with overcoming any technical barriers.

"But, you've got somebody there you can speak to then say, right I'm having a problem, I've done such and such and I can't register me steps or whatever, it's just saying, right, you should do this or I'll get somebody to ring you back and tell you what to do, you can't do that on text can you?" [R5]

Participants reported that the system provided continued support and encouragement, for example, the 'reminder texts' were helpful prompts to continue self-monitoring, and continued goal setting and immediate feedback provided further motivation to be active.

"It's quite nice. It keeps me sort of in the zone in the fact that I enjoy using the pedometer because it keeps my mind on exercise. I'm conscious of it, and, you know, if I haven't done too much moving about, I go and walk some more." [R5]

"I usually do remember to put me pedometer on...but as I say it's nice to know there's a reminder there and when I send off my figures I get an immediate response. I think it's all been quite encouraging actually." [R4]

They reported that the frequency of messages (at most two per week) to be sufficient for the 8-week period, but commented that over time the messages could decrease in frequency as they would not need as much reminding.

"As I say I think at the beginning you need more frequent reminders, you know I think you've got that right, and then as it goes on you don't need so many" [R6]

Overall, participants were positive about the text-message content, readability and clarity, and struggled to recall examples of discouraging messages. Several participants picked out the 'feedback texts' and 'motivational texts' - which provided instructions (tips) for increasing PA - as particularly useful.

"Do you know I've even started...this is what you have got me doing...when I'm on the kitchen chair, making a cup of coffee or something, I start running on the spot for a hundred! I count up to a hundred, running on the spot. So that's another hundred steps!" [R10]

Those who did not consistently increase their step counts reported receiving slightly more "negative" messages, but none was perceived as chastising.

"I found that very encouraging. It was good. When I'd done a good week, it's very... I only missed one week, and although you didn't down me, you didn't say anything nasty, you just said try a little harder, I know it's hard to get the exercise in, so I found it very encouraging." [R1]

Technical Issues

Nine out of 11 participants received the full regimen of text-messages as intended. Minor technical glitches impeded the full delivery to two participants. Most participants had no difficulty registering with the text-system, and more than 90% of all incoming messages from the participants were correctly formatted. Almost all participants responded to at least two 'prompting texts', so received tailored feedback on at least two occasions. Three-quarters responded to all 'prompting texts' and received tailored 'feedback texts' every week.

Several participants were unclear about the type of messages that they could respond to. Some sent "thank-you" messages in response to the 'feedback texts' and received a text-message stating "unrecognised format".

"I was just replying to your request or your advice, when I didn't do the correct steps one week, you gave me a couple of bits of helpful advice and I text back thanking you for that, and obviously it wouldn't let me send." [R7]

Related to this, participants wanted a greater degree of flexibility in the format for texting in step counts. They were asked to enter the word “steps” followed by their weekly step total, but some submitted only numbers or the word “step” or “step-count for week”, which triggered an unrecognised response text.

Finally, participants with limited experience of texting reported receiving and reading texts without problem, but engaged help from relatives (usually grandchildren) when prompted to text in their weekly step counts.

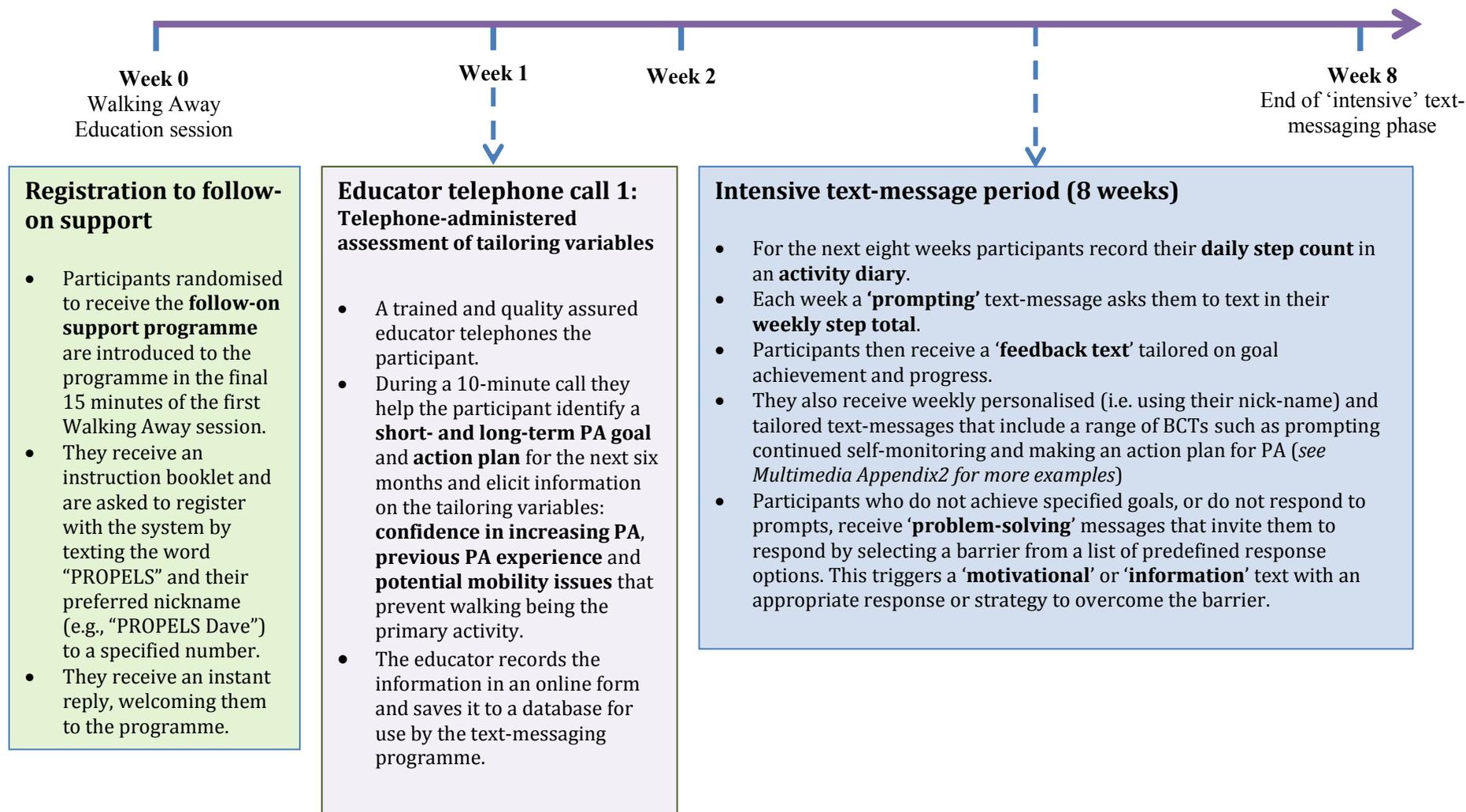
“Oh, yes, I could [read all the messages]...it’s just getting them sent off. Because again I think this week I was late, I thought I’d sent them in twice and then I had to check with [granddaughter], and I think I had pressed some other button. I think I’ve got a handle on it now. It sounds stupid but they didn’t have all these phones back then.” [R2]

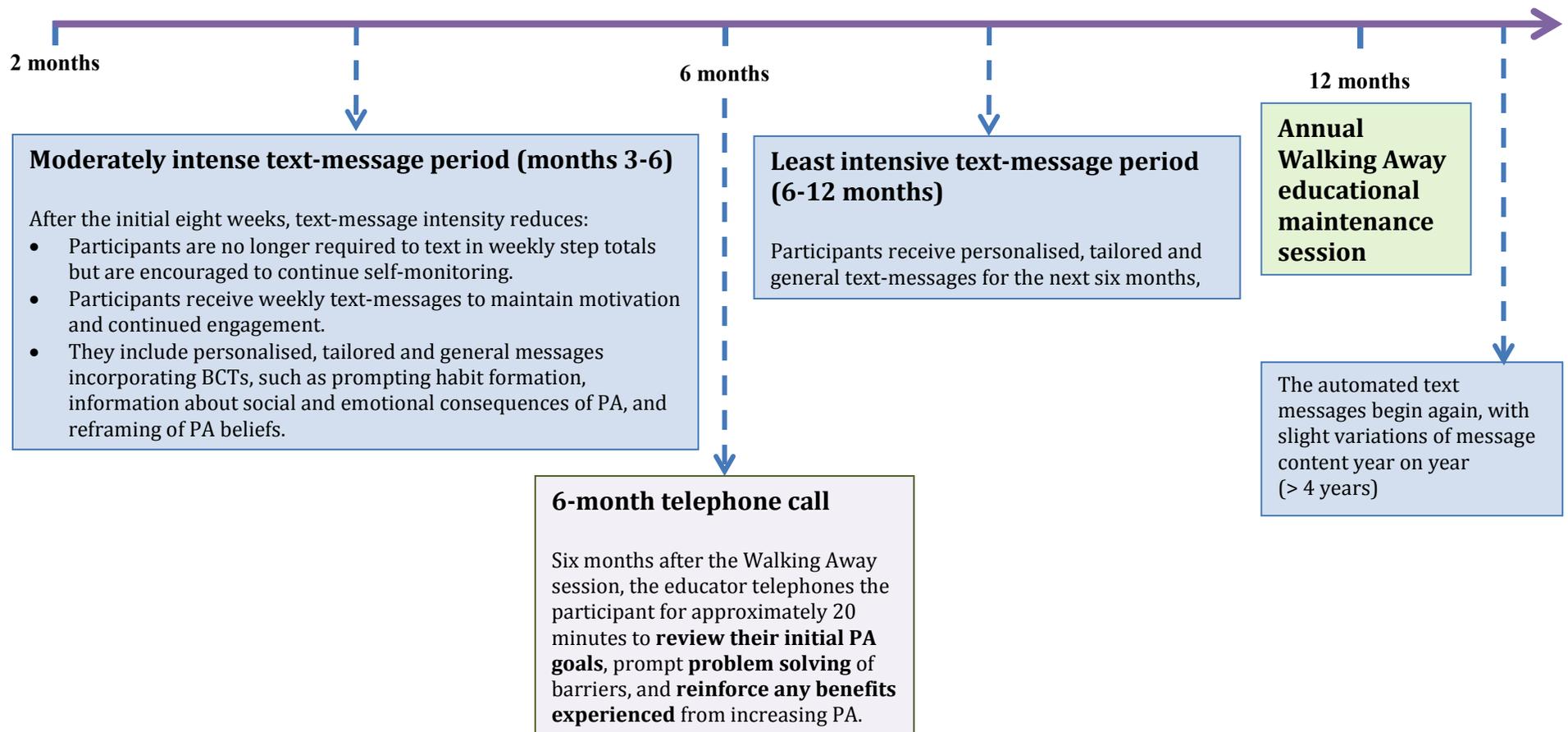
In sum, the piloting phase indicated that (a) the structure of the follow-on support (including the brief telephone call) was acceptable, (b) the frequency of text-messages over the 8-week pilot phase was acceptable, but should be reduced over time, (c) the content and language used in the text-messages was acceptable, (d) minor technical issues needed to be resolved and (e) participant instructions in both the Walking Away session and the follow-on support booklet required refinement.

The final PROPELS follow-on support programme

The findings from each phase were consolidated into a finalised set of text messages and underpinning schedule with integrated tailoring. This involved the development of tailoring matrices for each week of the programme – with additional messages for years 2-4 (to ensure that there was sufficient variation in message content for the 4-year study). We briefly describe each component of the resulting PROPELS RCT follow-on support programme in Figure 4.

Figure 4: The final PROPELS follow-on support programme overview





Discussion

Principal Results

Using a systematic approach to the development and piloting of the PROPELS text-messaging and pedometer follow-on support programme, we identified the following key components: differing frequency of text-messages according to period and year of programme; tailored text-message content according to key variables; personalised text-messages using the participant's nick-name; facility for two-way interaction; use of motivational texts emphasising affective benefits rather than health benefits, and inclusion of general encouragement messages. Participants' need for social support from, and rapport with the educator, and the need for a way of eliciting information for tailoring, resulted in the inclusion of supplemental telephone calls. Furthermore, we identified and addressed potential barriers such as impersonal messages or unfamiliar technology.

A key task was to assess the acceptability of a text-messaging intervention for our target group – older adults at risk of T2D. Their active involvement in the intervention development phases resulted in specific components to meet their needs. For example, an instruction booklet about the text-messaging programme and telephone calls to supplement the text-messages were added to the follow-on support programme to facilitate user engagement. We acknowledge that some initial training or help with text-messaging (at the initial Walking Away education session) may be required to ensure that *all* participants are able to engage with this type of text-messaging support. Automated tailored text-messaging following structured group education enables initial one-to-one help with getting started on the follow-on support text-messaging programme, but also reduces the time commitment for healthcare professionals and participants. It is scalable and fits into participants' everyday lives, while maintaining ongoing support following the initial education session. This is particularly important in primary care, where many people are identified as being at risk through health checks (e.g. NHS Health Check, in England [51]) but where there is limited capacity for providing ongoing support for behaviour change. In England, a key objective of the NHS five year forward view [52] is to implement a scalable diabetes prevention programmes; if successful, the PROPELS intervention may be an ideal candidate for this. Future research could explore variations of follow-on support, for example, providing the follow-on support as a standalone intervention, or pairing the follow-on support with a one-off telephone call that covers the Walking Away education session content for people who are unable or unwilling to attend group-based structured education.

The PROPELS text-messaging and pedometer follow-on support could be adapted fairly easily for other target groups such as people with newly diagnosed or established T2DM attending structured education (e.g. DESMOND [53]), or people with or at risk of other conditions (e.g., cardiovascular disease) where increasing PA reduces the risk of developing the condition or its consequences.

Limitations

Time constraints related to timelines of the PROPELS RCT [30] meant that we were unable to conduct a pilot of longer duration to test the acceptability of varying text-messaging frequency, participant engagement and retention over time. These are

assessed in the PROPELS RCT alongside PA outcomes [30]. Further qualitative work embedded within the RCT may identify potential future adaptations and facilitate long-term implementation and could provide an in-depth understanding of how participants engage with the programme over time, components that are most and least helpful, and how pedometer use, text-messages and telephone calls influence PA change over time.

We acknowledge that especially in developed countries, text-messaging may become less acceptable over time and participants may prefer newer technologies, such as smartphones that incorporate accelerometers. The relatively low ownership of smartphones in older adults [18] was supported by our formative work, and recent research indicates that text-messaging is becoming increasingly popular with older adults [54]. Taken together, this indicates that mHealth interventions through smartphones would have had limited reach for the PROPELS study at present, and a predominantly text-message focused programme is currently more acceptable. One advantage (and direction for future work) of the current PROPELS follow-on support programme is that it could be easily adapted in order to be delivered across a variety of platforms (e.g., via email, through an app) which would allow people to choose which version they use.

A final (potential) limitation relates to the *weekly* reporting of steps. Although PROPELS participants are encouraged to record their daily step count in their activity diary and text in the weekly total, there is potentially more room for error – in comparison to, for example, texting in each day's total in response to a daily prompt. However, our participants voiced aversion to the idea of daily texts as overkill and off-putting. Future qualitative work in the PROPELS trial may provide an insight into participants' experiences and preferences for self-monitoring their step count.

Comparisons with prior work

We developed a novel, interactive programme, whereby participants self-monitor their PA using a pedometer, text in their weekly step count and receive automated tailored feedback on goal achievement and progress. Previous mHealth interventions for T2DM prevention included untailored, passive text-messaging content such as information about T2DM risk (e.g., [20]).

The methods that we employed to develop the PROPELS follow-on support programme combine features of published mHealth development frameworks [31,32], and multiple iterative phases of qualitative research (similar to a user-centred design process [55]). The high level of engagement with our target population enabled refinements in the design to optimise its acceptability to users.

Robust development of mHealth behaviour change interventions can be time-consuming [33,56], and is often allocated limited time in RCT protocols. A potential consequence of rapid development is that insufficient attention is given to the underpinning theory and evidence base, or the selection of active ingredients (BCTs). Given the time constraints of the PROPELS RCT protocol (12 months to conceptualise, develop and test the follow-on support programme prior to the RCT's commencement), this paper provides a detailed outline of a pragmatic framework for developing and piloting a text-messaging intervention that draws on relevant behaviour change theory

and uses rigorous qualitative methods incorporating user engagement. It encourages replication and application to the development of similar interventions.

Conclusions

We developed a feasible and innovative text-messaging and pedometer programme based on evidence and behaviour change theory and grounded in the experiences, views and needs of people at high risk of T2DM. A large scale RCT is testing the effectiveness of this four-year programme over and above group-based structured education alone.

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WH, SS and HE designed the initial protocol for the follow-on support component of the PROPELS intervention. KM and HE designed the methodological approach of the development and pilot study and collected and analysed the data used to develop and refine the follow-on support programme. SS developed the computer program to generate and send the tailored text-messages and the web-based interface. KM, JT and WH developed the curriculum and training to support educators with the delivery of the follow-on support intervention and led on developing materials for assessing quality in delivery. KM and HE co-led writing the manuscript with extensive input from WH, JT and SS. All authors contributed to, read and approved the final manuscript.

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Competing interests

KM, SS, JT, TY, SG and HE declare that they have no conflicts of interest. WH has undertaken consultancy work for AbbVie Ltd. MJD has acted as consultant, advisory board member and speaker for Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim, AstraZeneca and Janssen and as a speaker for Mitsubishi Tanabe Pharma Corporation. She has received grants in support of investigator and investigator initiated trials from Novo Nordisk, Sanofi-Aventis and Lilly. KK has acted as a consultant and speaker for AstraZeneca, Boehringer Ingelheim, Janssen, Lilly, MSD, Novartis. Novo Nordisk and Sanofi. He has received grants in support of investigator initiated trials from AstraZeneca, Boehringer Ingelheim, Lilly, Novartis, Novo Nordisk, Roche and Sanofi.

Abbreviations

BCT: behaviour change technique;

IGR: impaired glucose regulation;

NHS: National Health Service;

PA: physical activity;

RCT: randomised controlled trial;

SMS: short message service;

T2DM: Type 2 Diabetes.

Multimedia Appendices

Multimedia Appendix 1: Key findings from Phase 1–Intervention objectives, determinants of physical activity targeted in the PROPELS follow-on support programme, and included behaviour change techniques

Multimedia Appendix 2: Tailoring matrices examples

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Appendix 1: Key findings from Phase 1–Intervention objectives, determinants of physical activity targeted in the PROPELS follow-on support programme, and included behaviour change techniques.

Intervention objectives of the PROPELS follow-on support programme	
Primary objectives:	Enhance the use of self-regulatory strategies to increase PA.
Secondary objectives:	Make the benefits of PA personally relevant (positive attitudes and beliefs).
	Ensure that participants are motivated to increase and maintain their PA.
	Enhance positive outcome expectancies and self-efficacy in relation to PA.

Determinants of behaviour change	How will we achieve this?	BCTs included (in final programme)	Intervention component in which this BCT occurs		
			(Walking Away session)	Follow-on support Text-messages	Phone call
1. Self-regulatory strategies	1.1 Encourage participants to set short- and long-term PA goals.	1. Goal setting (behaviour)	X		X
	1.2 Encourage participants to develop action plans (and reinforce these over the course of the follow-on support programme).	2. Action planning	X	X	X
	1.3 Encourage and reinforce self-monitoring (wearing the pedometer and logging steps).	3. Self-monitoring of behaviour	X	X	
	1.4 Provide feedback relating to goal achievement and progress.	4. Feedback on behaviour		X	X
	1.5 Highlight the discrepancy between current behaviour and goals.	5. Discrepancy between current behaviour and goal		X	X
	1.6 Review initial PA goals and amend these accordingly.	6. Review behaviour goals			X
	1.7 Help participants to overcome barriers to increasing their PA	7. Problem solving		X	X

2. Attitudes and beliefs	<p>2.1 Reinforce health, emotional and social benefits of increasing PA (e.g., persuade that increasing PA will make participants feel better generally and also reduce risk of T2DM).</p> <p>2.2 Highlight that by increasing PA by even a small amount can have numerous health benefits.</p> <p>2.3 Encourage participants to reflect on the benefits and negatives of changing their behaviour</p>	<p>1a. Information about health consequences</p> <p>1b. Information about social consequences</p> <p>2. (Re)framing</p> <p>3. Pros and cons</p>	<p>X</p> <p>X</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p>	
3. Motivation	<p>3.1 Provide positive reinforcement regarding progress and achievement of PA-related goals.</p> <p>3.2 Encourage plans to reward oneself (appropriately) if goals are achieved.</p> <p>3.3. Encourage PA with others to stay motivated.</p> <p>3.4 Encourage alternative activities to help participants stay motivated to meet their step goals.</p> <p>3.5 Promote positive self-talk.</p> <p>3.6 Encourage the use of visual cues and prompts.</p> <p>3.7 Encourage ways of enabling PA to become habitual in participants' lives.</p> <p>3.8 Encourage participants to make a commitment to increasing (or maintaining) their activity.</p>	<p>1. Social reward</p> <p>2. Self-incentive</p> <p>3. Social support (practical)</p> <p>4. Instruction on how to perform the behaviour</p> <p>5. Self-talk</p> <p>6. Prompts/cues</p> <p>7. Habit formation</p> <p>8. Commitment</p>	<p>X</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p>	<p>X</p>
4. Self-efficacy and Outcome expectancies	<p>4.1 Ensure participants feel supported.</p> <p>4.2 Help participants believe that they are able to overcome barriers in order to stick to action plans and achieve goals.</p> <p>4.3 Help participants to focus on past success if previously physically active.</p> <p>4.4 Promote imagining of future outcomes (being active versus inactive)</p>	<p>1. Social support (emotional)</p> <p>2. Verbal persuasion about capability</p> <p>3. Focus on past success</p> <p>4. Comparative imagining of future outcomes</p>	<p>X</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p>	<p>X</p>

Appendix 2: Tailoring matrices examples

Matrices and content for WEEK1 text messages								
If no response (after 24 hours)								
Previous PA?	msg		Content	Text message	Cnt	Text description	Trigger/timing	
yes	nr01		n/a	Hi #name12345# Remember to reply with your weekly step count total :-). Monitoring your activity is the first step in becoming active again!	139	noresponse1	If no response to 'text-in' within 24 hours	
no	nr02		n/a	Remember to reply with your weekly step count total :-). It doesn't matter what your count is- monitoring your activity is the first step to getting active!	154	noresponse2	If no response to 'text-in' within 24 hours	
aa								
Achieved LT GOAL (i.e., >21,000 steps/week above baseline)	Achieved ST GOAL (i.e., >3,500steps/week above baseline)	msg						
yes	n/a	aa01	Motivation	Congratulations! You have achieved your long term goal of approx. XXXXX per day-that's XXXXX more per week than when you started!Well done and keep it up :-)	157	positive reinforcement1	Straight after reply with step count	
no	yes	aa02	Motivation	Congratulations #name12345# on achieving your short term goal.You have increased by roughly XXXX steps per day-that's XXXX more per week than when you started!	159	positive reinforcement2		
	no	aa03	Self-Regulation	Thanks for the text #name12345# Keep wearing your monitor and logging your steps and try to make small changes so that you reach your goal next week :-)	152	selfmonitor reminder1		

Matrices and content for WEEK4 text messages																				
If no response (after 24 hours)																				
msg																				
nr03																				
ea																				
Previously met LT GOAL?	Goal Progress ?	Met LT GOAL this week?	Previously met ST GOAL?	Goal Progress ?	Met ST GOAL this week?	msg	Content	Text message	Cnt	Text description	Trigger/timing									
yes	Increased >3,500 steps from week 3	n/a				ea01	Motivation	Congratulations #name12345# - you have continued to increase your weekly physical activity! That's fantastic progress.....keep up the hard work :-)	146	positive reinforcement3	And yet again you manage to keep increasing your activity :-)									
	Maintained previous week (+/- 3,499)	n/a				ea02	Motivation	Hi #name12345# Well done for maintaining your weekly step total - we realise how tough this can be each week! You are making fantastic progress - keep it up :-)	160	positive reinforcement4	And yet again you manage to maintain your activity :-)									
	Decreased >3,500 steps from week3	n/a				ea03	Self-Regulation	Thanks for the text! You decreased slightly from last week but not to worry-keep making small changes and you will soon be achieving your goal every week :-)	157	goal discrepancy1	Thanks! You decreased slightly from last week but keep making small changes and you will soon be back on track and getting closer to your long term goal :-)								goal discrepancy2	
no	n/a	yes	n/a			ea04	Motivation	Congratulations! You have achieved your long term goal of approx. XXXXX per day-that's XXXX more per week than when you started!Well done and keep it up :-)	157	positive reinforcement1										
				Increased since last week >1000 steps	n/a	ea05	Motivation	Congratulations again! You have continued to increase your weekly steps which is brilliant - well done!	103	positive reinforcement8										
			yes	Maintained last week (+/- 999 steps)	n/a	ea06	Motivation	Congratulations! You have managed to maintain your weekly steps which is brilliant - keep making small changes to get one step closer to your long-term goal :-)	160	positive reinforcement9										
			no	Decreased since last week >1000 steps	n/a	ea07	Self-Regulation	Thanks! You decreased slightly from last week but keep making small changes and you will soon be back on track and getting closer to your long term goal :-)	156	goal discrepancy2										
					n/a	yes	ea08	Motivation	Congratulations #name12345# on achieving your short term goal.You have increased by roughly XXXX steps per day-that's XXXX more per week than when you started!	159	positive reinforcement2									
						no	ea09	Self-Efficacy	Thanks for the text :-) We realise that increasing your activity can be really tough. We'll contact you shortly to try and provide some helpful suggestions.....	158	support problemsolve2									
eb																				
A/P includes gym?	Achieved LT GOAL (i.e., >21,000 steps/week above baseline)	Achieved ST GOAL (i.e., >3,500steps/week above baseline)	Confidence	Serious mobility problem? Y/N?	msg															