Study Protocol

Promoting physical activity and exercise after stroke using a text messaging intervention (Phase 2)

Trial/Study Acronym	KATS (Keeping Active with Texting after Stroke)
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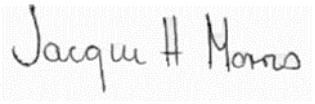
PROTOCOL APPROVAL

Signatures

The undersigned confirm that the following protocol has been agreed and approved by the Sponsor and that the Chief Investigator agrees to conduct the trial/study/study in compliance with this approved protocol and will adhere to the principles of GCP, the Sponsor SOPs, and any other applicable regulatory requirements as may be amended from time to time.

JACQUI MORRIS		16.02.2021
Chief Investigator	Signature	Date

LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CHSS	Chest Heart and Stroke Scotland
CNORIS	Clinical Negligence and Other Risks Indemnity Scheme
CRT	CRT Core Research Team
CWG	Collaborative Working Group
GCP	Good Clinical Practice
ICF	Informed Consent Form
IF	Incidental Findings
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SIMD	Scottish Index of Multiple Deprivation
SMS	Short Message Service
SOP	Standard Operating Procedures

SUMMARY

Note: This protocol is for Phase 2 of the study only (Phase 1 (now complete) did not require NHS research ethics review and approval, as confirmed by the sponsor). A summary of Phase 1 is given to provide necessary background information on the theoretical and empirical basis of the intervention being tested and the methods used in its design and development (Appendix 1).

The overall aim of the study is to co-design, develop, pilot and refine a novel Short Message Service (SMS) intervention to promote physical activity among stroke survivors. The intervention uses text messages to provide support to stroke survivors at the end of their rehabilitation period to facilitate the uptake and maintenance of physical activity.

In Phase 1 we developed the novel intervention through co-production with stroke survivors and other key stakeholders using the Collaborative Working Group methodology.

Phase 2, for which we are seeking approval, will pilot the intervention it in two waves to further develop and refine it through consultation with the study participants and a Collaborative Working Group (CWG). The main output from the Phase 2 will be an intervention for evaluation in a future randomised controlled trial.

Study Title	Promoting physical activity and exercise after stroke using a text messaging intervention (Phase 2)
Study Design	Pilot testing and refinement of a novel behaviour change intervention using Collaborative Working Group methodology
Study Population	Stroke Survivors
Sample Size	44 stroke survivors (Wave 1: 14, Wave 2: 30)
Planned study Period	Phase 1: 4 months (not included in this application) Phase 2: 19 months Phases 1 and 2: 23 months in total
Intervention period	12 weeks
Follow up phase duration	None
Objectives	To co-design, pilot and refine a novel Short Message Service (SMS) intervention to promote physical activity among stroke survivors.
Inclusion Criteria	Community dwelling stroke survivors who: • Are over 18 years of age • Have access to and can use a mobile phone • Can provide informed consent • Have no medical contraindications to increasing physical activity • Have completed a session on goal setting with a therapist at the end of their community rehabilitation
Exclusion Criteria	Stroke survivors who: • Are unable to participate in the study over a 12 week period • Are unable to provide informed consent for participation • Cannot communicate verbally over the telephone or face to face (feedback is required for intervention development)

1 INTRODUCTION

The purpose of this study is to co-design, develop and refine a new Short Message Service (SMS) behavioural intervention with stroke survivors, to support them to continue with exercise and physical activities that facilitate recovery goals, health, and fitness after discharge from rehabilitation. Stroke is a major cause of adult disability (1) and places a high burden on survivors, families, and health services. There are 1.2 million stroke survivors in the UK, with 100,000 individuals annually experiencing new stroke, leading to societal costs to the UK of £26 billion annually (2). At 2.2% of the population, Scotland has the highest stroke prevalence of all UK nations (2). Seventy percent of survivors experience physical, communication, or cognitive impairments that persist after hospital discharge and limit walking, leisure activities, activities of daily living, and quality of life (3). With global stroke incidence expected to rise by 123% in the next 15 years (2), reducing personal and societal impact of stroke is a priority.

2 BACKGROUND AND RATIONALE

Maintaining and improving physical recovery and health after stroke requires high intensity repetition of task-orientated rehabilitation exercises (4) and participation in a range of diverse physical activities for aerobic fitness, strength, and balance (5). Rehabilitation delivered by physiotherapists is the main intervention for physical recovery immediately after stroke, however it is resource intensive and time limited (4). After rehabilitation, survivors are signposted to community-based exercise opportunities, walking groups and gyms, and are prescribed home exercises to support recovery.

Despite this, 50% of stroke survivors report feeling abandoned (2) and struggle with adherence to exercises for ongoing recovery (6). Indeed, as many as 65% of stroke survivors do not fully adhere to home exercise programmes, and 35% do not adhere at all (7). Despite systematic review evidence supporting physical activity (PA) for mobility, health, and secondary stroke prevention (5), stroke survivors' energy expenditure and mean daily step counts are half those of age-matched peers (8, 9). Our systematic review has shown that tailored behavioural interventions post-stroke can increase adherence to PA and exercise programmes (10), however optimal characteristics of these interventions remain unclear (11).

There are good theoretical reasons, but little empirical evidence, suggesting Short Message Service (SMS) messages for delivery of tailored behavioural interventions may support exercise and PA adherence after rehabilitation. SMS can deliver timely, effective, cost-effective, automated, brief support messages to prompt initiation and maintenance of PA in general populations (12) and older adults (13). SMS messages can be tailored, require minimal technology literacy or internet access, are immediate, can be re-read, and directly delivered to the recipient, unlike smartphone and tablet applications that have to be sought (14). In the UK, SMS messaging is almost universal across ages, socio-economic spectrum and ethnicities (15). SMS messaging is widely used in the Scottish NHS to support a range of health behaviours (16) and provide a cheap and scalable mode of intervention delivery which does not require a smart phone, internet access or a high degree of electronic literacy.

Interventions involving smartphone and tablet applications and wearable technologies have been tested with stroke survivors. However, observational studies, randomised controlled trials and meta-analyses have shown that effects on PA behaviour and outcomes are equivocal at best (17, 18). The authors concluded that complexity of the technology may have influenced outcomes in a population that is likely to have cognitive, communication and physical disabilities. The focus of studies in those reviews on exercise instruction rather than on personalised, theory-based behavioural interventions to enhance motivation and change behaviour is also likely to have contributed to the equivocal outcomes (18). However, behavioural interventions delivered in person (face-to-face or remotely such as via phone) are resource intensive and have limited reach. There is a clear imperative to develop behavioural

interventions to promote uptake and adherence to post-rehabilitation exercise and PA that can be delivered through universally available, simple to use, accessible technology such as SMS messaging.

Communication and staying connected with others is very important to stroke survivors (19). Our pilot work for this study and other qualitative research exploring stroke survivors' use of mobile phones confirms the importance and universality of SMS messaging to people with stroke, highlighting it as their first and main use of technology, even if they do not go on to use other types of technology (20). Importantly for our purpose of increasing adherence to exercise and PA, survivors value texts as reminders to plan and participate in important activities, and for communication (19, 20). This reflects our pilot work, which highlights that many stroke survivors view SMS messaging as a useful tool that is accessible and easy to use, which they use regularly anyway, and see as a potential avenue for delivery of a valuable motivational intervention to continue supporting them after rehabilitation.

SMS messaging for motivational support has not yet been widely tested in stroke survivors and presents an untapped tool. Three studies have examined SMS as an adjunct to rehabilitation, none of them in the UK. One Australian pilot study with participants 12-24 months post-stroke showed potential effects of behaviour change techniques delivered via SMS messaging, to achieve multiple self-management goals, but was conducted too late after rehabilitation to provide the continuity survivors seek (21). Furthermore, the intervention was designed by expert stakeholders, rather than through co-design with stroke survivors. Two small observational studies in Sweden and Uganda, (22, 23) involving 15 and 16 participants respectively, have provided SMS delivered reminders and exercise instructions, but without explicit inclusion of behaviour change techniques. The studies show accessibility of SMS messaging for stroke survivors, but none was co-designed with users, to ensure the intervention fits with users' contexts and needs. Messages were directive, rather than being drawn from and relevant to survivors' experiences and personal goals, as we propose in this application.

Several features are novel and innovative about the proposed research. First, delivery context of the intervention within rehabilitation is unique in providing the missing link between the end of scheduled rehabilitation and self-care in the community, when stroke survivors in the UK report strong feelings abandonment (24). Secondly, the two target behaviours of prescribed exercises to promote recovery *and* lifestyle physical activities provide meaningful and tailored intervention targets, whilst simultaneously supporting the initiation and maintenance of physical activities. Thirdly, developing a theoretically informed SMS messaging intervention in stroke rehabilitation has not previously been undertaken. Fourth, the rural locations in Scotland, in which many stroke survivors live further justifies this unique approach to addressing their sense of abandonment. Finally, co-design of the intervention with stroke survivors and rehabilitation professionals is innovative in deliberately and systematically incorporating features they feel are relevant to survivors' needs.

3 STUDY OBJECTIVES

The aims of this study are:

1. To co-design with stroke survivors, their family/friends, and rehabilitation professionals, a novel, theoretically informed behaviour change intervention, comprising a series of SMS messages, to support community dwelling stroke survivors to adhere to personal exercise and PA goals for recovery (Phase 1, complete[not part of this application]).
2. To pilot test and refine the intervention ready for evaluation in a future feasibility randomised controlled trial (Phase 2)

4 STUDY DESIGN

4.1 INTERVENTION

The SMS intervention is designed to support goal achievement and help the stroke survivors set their own goals for physical activity and recovery going forward at the end of rehabilitation. It will provide real-time support for goal setting, planning and self-monitoring of physical and recovery specific exercises and activities. It will also enhance motivation, combat the feeling of abandonment and support the uptake and maintenance of physical and recovery specific exercises and activities. Participants will also receive a study handbook and calendar. The handbook *(Handbook)* is a reference document to reinforce the main components of the intervention, while the calendar *(Calendar)* is provided so that participants can self-monitor their activities during the intervention period. The calendar is for the participants' use only. It will not be used as a data collection tool. Participants will be informed that the calendar is for their own use only and will not be collected at the end of the intervention period.

The SMS intervention will be delivered to participants over a period of 12 weeks. Prior to recruitment, potential participants will discuss their post-rehabilitation goals with their physiotherapist or occupational therapist (normal rehabilitation practice) in person, or by telephone (COVID regulations depending).

The intervention was developed in Phase 1 using iterative co-design processes and guided by the MRC Framework for Complex Interventions (32). The Core Research Team (CRT), worked with a Collaborative Working Group (CWG) to co-design the intervention. (Appendix 1 provides more detailed information about the theoretical and empirical basis of the intervention, the methods used in its development and how the CWG works).

A summary description of the text message intervention is given below

Early text messages are designed to foster interest in the study and emphasise the benefits of physical activity and recovery specific exercises and activities to achieve post-rehabilitation goals after stroke. They encourage participants to continue to work towards the goals agreed with their therapists and give support to undertake prescribed exercises. These are followed by messages to increase motivation and create intention to become more active when rehabilitation services stop. The next group of messages encourage commitment to setting goals going forward and making specific action plans. The messages also encourage identification of barriers to changing behaviour and the development of coping strategies. The final messages are designed to increase self-efficacy for long-term maintenance of physical activity and recovery specific exercises and activities. The messages are augmented with information about opportunities to be physically active and encourage engagement in activities to achieve their rehabilitation goals and with online resources. The messages also provide support and reminders to be physically active and to engage in activities. To maintain engagement with the intervention, anonymised quotes from other stroke survivors about their experiences and the benefits of engaging in activity will be included. To encourage interaction and as a method of monitoring engagement some messages will be questions. *(SMS Intervention)*. The intervention was developed with a speech and language therapist and with stroke survivors with aphasia, to ensure it can be universally accessed by people after stroke.

The SMS intervention will be revised iteratively in Phase 2. It will initially be pilot tested with 14 stroke survivors in Wave 1. It will then be tested with another 30 participants in Wave 2 following revisions and refinement.

The intervention will be revised using Collaborative Working Group methodology. The Collaborative Working Group (CWG) which co-designed the intervention in Phase 1 will also work with us at key points in Phase 2. The CWG comprises eight stroke survivors from existing PPI groups, seven physiotherapists, two representatives from stroke organisations including Chest Heart and Stroke Scotland (CHSS) and the Stroke Association and eight

academics with a special interest in stroke, rehabilitation, biomechanics, clinical trials and speech and language therapy. The CWG will consult with the Core Research Team (CRT) which comprises the Principal Investigator and all study co-investigators to review data at the end of Waves 1 and 2 to modify the intervention.

As the intervention is still being refined, no comparator group will be used in Phase 2.

4.2 SAMPLING AND RECRUITMENT

Recruitment will take place in two waves: in Wave 1 recruitment and intervention delivery will last for 5 months with 14 participants being recruited, while in Wave 2 recruitment and intervention delivery will last 19 months, when 30 participants will be recruited. Three months will be allowed for analysis and intervention adaptation between the Waves. Recruitment of individual participants will involve a two-stage process.

Stage 1

The researcher will work with rehabilitation and nursing staff in stroke and stroke rehabilitation services in Tayside and Grampian to identify patients at the point of hospital discharge to a community setting. Patients who have a diagnosis of stroke, who are deemed by rehabilitation therapists as able to participate in PA and ongoing rehabilitation exercises, who have the ability to use a mobile phone and have access to a mobile phone will be invited to consider taking part in the study after they have been discharged home. They will be given information about the study and invited to provide informed consent to be contacted by the study researcher approximately 4 weeks after discharge *(Expression of interest form)*. The therapist will pass the potential participants' contact details to the researcher.

The researcher will also work with community therapists and nurses, to identify and invite people who have already been discharged from hospital i.e. people who had not been approached in hospital, but may be eligible for inclusion. These individuals will be invited in the same way and will be asked to give consent to be contacted at the end of their community rehabilitation period *(Expression of interest form)*.

Stage 2

Around four to eight weeks post-discharge, stroke survivors who have given consent to be contacted, will be invited, by the researcher in a telephone call, to be recruited into the study when they are nearing the end of their community rehabilitation programme. Those confirming their interest will be given the full Participant Information Sheet *(PIS)*. With the stroke survivor's permission, the researcher will liaise with the community therapist to confirm that the stroke survivor is eligible for inclusion in the study. The therapist will also be asked to provide information about the types of goals and exercises the stroke survivor has been working on *(Participant referral form), (*again with permission). The researcher will then contact the stroke survivor by telephone again to answer any questions and find out if he/she is still interested in taking part. Those willing to take part will be recruited by the researcher by telephone. We have successfully obtained informed consent by telephone in a previous study with stroke survivors (CSO HIPS/17/03, The We Walk Study). For this method, participants will be sent a copy of the consent form (by email or post). The consent form *(Consent form*) will be completed by the researcher during a recorded telephone call, and the date and time of consent will be recorded. A copy of the consent form signed and dated by the researcher will be sent to the Participant (by email, WhatsApp or by post).

4.3 INTERVENTION DELIVERY

Following recruitment, the personalised SMS messaging intervention will be delivered over 12 weeks. Messages will be sent by an automated computer system which will be programmed to send out text messages to participants' mobile phones in a predetermined sequence. Participants will be given the opportunity to stop the intervention at any time.

In addition to the SMS intervention, participants will receive a study handbook and calendar. The handbook *(Handbook)* is a reference document to reinforce the main components of the intervention. It will also provide information and links to online resources that offer exercises for people who have had a stroke. The calendar *(Calendar)* is provided so that participants can self-monitor their activities during the intervention period. This calendar is for the participants' use only. It will not be used as a data collection tool. Participants will be informed that the calendar is for their own use only and will not be collected at the end of the intervention period.

4.4 DATA COLLECTION AND ANALYSIS

Analysis of the qualitative data collected in Phase 2 will be ongoing and iterative to inform the refinement of the behaviour change intervention, and how it can be delivered.

Participant data

Baseline assessment
The study researcher will conduct with participants a telephone baseline interview and will collect data on demographic characteristics, record current levels of PA and exercises and explore barriers to engagement with the intervention (*Baseline assessment*).

Intervention period
In waves 1 and 2, detailed field notes will be taken by the researcher at every contact with participants. Data on the recruitment processes, intervention delivery, liaison with participants' therapists and participant responses to the intervention will inform the study management and intervention content and delivery.

At six weeks post-recruitment, participants will receive a structured telephone interview from the RA, using a simple proforma schedule to explore and record participants' experiences and views on how the intervention is working "in-use" for them, as messages are delivered *(Interim interview schedule)*. Their views will be sought on intervention accessibility, acceptability, message tone, frequency, accessibility of web resources mentioned in the handbook, impact on physical activity and exercise and desired changes to the intervention. We will also seek their views on important outcomes, to determine measures to be used in a future trial. Participants will also be asked to consider the feasibility and acceptability of wearing a device to measure activity (accelerometer) for seven days at baseline and at the end of the intervention period.

Note: If Wave 1 participants feel that using an accelerometer would be feasible and acceptable, we may take a decision to use accelerometers in Wave 2. If such a decision is taken, we would apply for a substantial amendment to incorporate a change in protocol prior to Wave 2.

The interviews will be recorded and transcribed. Data will be analysed as it is collected, by two researchers, using Framework Approach.

Data on SMS delivery and responses from participants captured by the automated computer programme will be collated and anonymised by the Health Informatics Centre. These data will be analysed to monitor engagement with the study and with components of the behaviour change intervention.

End of intervention assessment
All participants will complete a telephone interview at the end of the intervention to collect data on theoretical targets, engagement and satisfaction with the intervention, and important outcomes, to inform the future RCT *(End of study evaluation)*.

On completion of the study, participants will be given a £20 gift voucher as recompense for using their mobile phone during the study.

Outcome Measures (Wave 2 only)

Outcome measures will only be collected for participants in Wave 2 to determine feasibility and acceptability of their use in a future trial. As this is an intervention development study, the measures will not be used to assess the efficacy or effectiveness of the intervention. The six short questionnaires listed below will be completed by Wave 2 participants during a telephone interview with the study PI as part of the baseline interview and final evaluation.

- Stroke Impact Scale
- EQ5D-5L
- The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
- IPAQ/Short form IPAQ
- Activities specific balance confidence scale
- Stroke Self-Efficacy Scale

Collaborative Working Group

The Collaborative Working Group (CWG) is a formalised stakeholder consultation process. It will meet on two occasions in Phase 2. CWG members are academics with expertise in the topic, allied health professionals who have volunteered from our clinical network contacts and stroke survivors from our established Patient and Public Involvement Group. The CWG method uses a structured decision-making matrix to guide discussion (30). The meetings will be chaired by the PI and the CWG and Core Research Team (CRT) will together work through rounds of mixed group discussion to reflect on key findings from the delivery of the intervention to make recommendation on how the intervention and its delivery should be modified.

End of Wave 1

The CRT and CWG will meet after the first cohort of 14 participants has completed the intervention and the data are analysed, to review new information obtained, using a structured discussion process involving the Questions: What? So what? and Now what?

- *What* has been will working well, or not so well, regarding the content, delivery and receipt of the intervention?
- *So what* are the implications for intervention design?
- *Now what* needs to change to improve the intervention (taking into account priority and feasibility)?

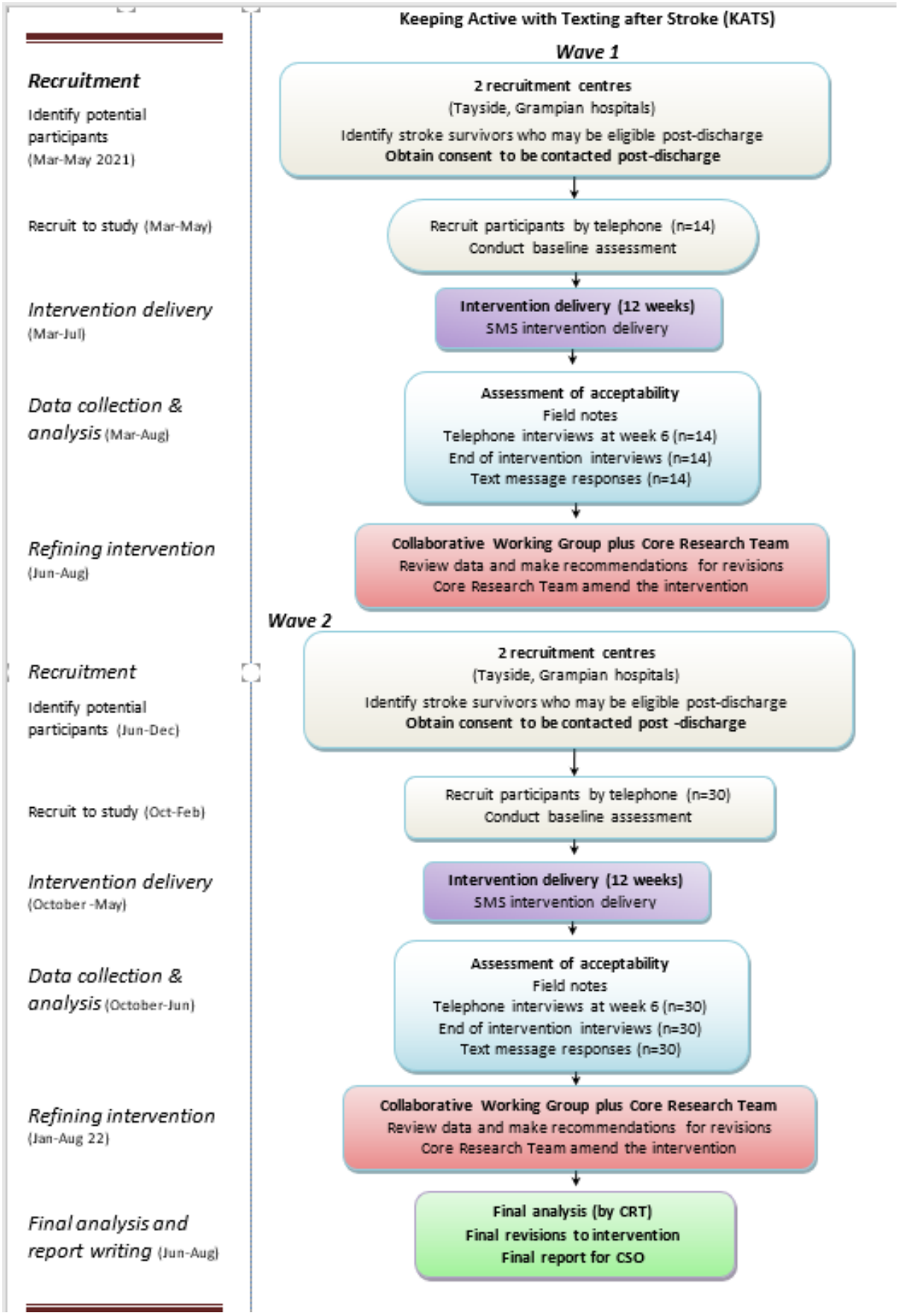
The CWG consultation process enables evaluation of how the intervention is working 'in-use' and determines changes that the research team will integrate into the intervention for wave 2 recruitment.

End of Wave 2

The CWG and CRT will again meet when Wave 2 has been completed and the data are analysed to finalise the refinement of the intervention. The same structured approach will be used for the meeting.

Outputs: By the end of Phase 2, final amendments, in the light of feedback, will have been made, to provide us with the final intervention and outcome measure battery to be used in a feasibility study and full-scale trial.

4.5 STUDY FLOWCHART



4.6 STUDY SAFETY ASSESSMENTS

Phase 2 involves increasing physical activity by people who are almost at the end of a rehabilitation programme after having a stroke. The stroke survivors may have impaired mobility and/or balance problems. However, those who are invited to take part will have been assessed by a health professional (usually a physiotherapist) before being invited to take part in the study, and will only be invited if it is deemed safe for them to take part.

Risks posed by COVID-19 are minimised, as all contact with participants will be by telephone and text communication.

Any adverse events will be recorded and serious adverse events will be reported according to the protocol.

4.7 TISSUE

Not applicable

4.8 INCIDENTAL FINDINGS

Any incidental findings (IF: previously undiagnosed condition) considered to be clinically significant will be reported to the participant's referring health professional or GP, with the consent of the participant.

4.9 TRIAL/STUDY POPULATION

The study population is made up of community dwelling stroke survivors who are nearing the end of community rehabilitation after stroke.

4.10 NUMBER OF PARTICIPANTS

40 - 50 stroke survivors

4.11 INCLUSION CRITERIA

Potential participants are stroke survivors who:

- Live in the community in Tayside or Grampian
- Are over 18 years of age
- Have access to and can use a mobile phone
- Can provide informed consent
- Have no contraindications to increasing physical activity
- Have discussed goal setting with their therapist before discharge from rehabilitation services

4.12 EXCLUSION CRITERIA

Stroke survivors who:

- Are unable to participate in the study over a 12-week period
- Have medical conditions contraindicating increased physical activity or specific rehabilitation exercises
- Cannot communicate verbally (over the telephone or face to face). These people will be excluded for this phase of the study because it involves providing informed consent, discussing the content of the intervention and giving advice on how to improve it, completing questionnaires by telephone.
- Are unable to give informed consent
- Individuals will not be enrolled to the study if they are participating in the clinical phase of another interventional trial/study or have done so within the last 30 days. Individuals who are participating in the follow-up phase of another interventional trial/study, or who are enrolled in an observational study, will be co-enrolled where the CIs of each study agree that it is appropriate

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 CONSENTING PARTICIPANTS

Consent for the study will be obtained in two stages. The researcher will work with hospital and community physiotherapists and stroke liaison nurses to identify patients who may be eligible to take part. Stroke survivors who are in hospital receiving rehabilitation will be asked if they would consider taking part in a study when they have been discharged from hospital and are nearing the end of a community rehabilitation programme. Community therapists and nurses will identify potential participants who have already been discharged. Stroke survivors who would like to consider taking part will be asked to give consent to be contacted by the researcher approximately four weeks after discharge from hospital, when they are nearing the end of community rehabilitation. Potential participants will be given a brief information leaflet and asked to give written consent to be contacted and to provide their contact details *(Expression of interest form).*

Stroke survivors who have given consent to be contacted will then be approached by the research staff when their rehabilitation programme is nearing completion. Again, the researcher will liaise with the community physiotherapist to ensure that it is appropriate to invite the individuals to take part in the study. Potential participants will be given Participant Information Sheets *(PIS*) and, will be invited to speak to a researcher by telephone, who will explain the study in full and answer any questions. For those willing to take part, the researcher will obtain consent by telephone. We have successfully obtained informed consent by telephone in a previous study with stroke survivors (CSO HIPS/17/03, The We Walk Study). Participants will be sent a copy of the consent form (by email or post). The consent form *(Consent form*) will be completed by the researcher during a recorded telephone call, and the date and time of consent will be recorded. A copy of the consent form signed and dated by the researcher will be sent to the Participant (by email, WhatsApp or by post).

The health professional who invited potential participants to take part will be informed if and when their patient has been recruited to the study *(Therapist letter).* The stroke survivors' GPs will also be informed when their patients have been recruited *(GP letter).*

Please note this study does not have a physician as part of the research team. We will give potential participants the opportunity to discuss the study with a Consultant Allied Health Professional/Physiotherapist Team Lead.

Where a participant requests to speak with the Consultant Allied Health Professional/Physiotherapist Team Lead about the study the consent process will not be completed until the participant has spoken to the consultant and had all their questions answered to their satisfaction.

For adults who lose capacity, the participant and all identifiable data collected would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

The informed consent process will be conducted in compliance with TASC SOP07: Obtaining Informed Consent from Potential Participants in Clinical Research

5.2 SCREENING FOR ELIGIBILITY

Potential participants will be assessed for eligibility at two stages:

1a. In hospital, when asked to consider taking part in the study when rehabilitation (hospital and community) is complete. Potential participants will be identified by a health professional who has been involved in their rehabilitation and care since they had a stroke.

1b. Potential participants who were not invited to take part when they were in-patients, will be screened for eligibility post-discharge (by a physiotherapist), when they are receiving community rehabilitation.

2. At the end of community rehabilitation (by a physiotherapist), when potential participants are contacted again to determine whether they want to be recruited into the study.

5.3 INELIGIBLE AND NON-RECRUITED PARTICIPANTS

Note will be taken of those unable or unwilling to participate, and reasons (if provided on a voluntary basis). No other involvement will be required. Personal details will not be recorded, only place identified and reason for non-participation (if volunteered).

5.4 RANDOMISATION As this is an intervention development study, participants receiving the intervention will not be randomised

5.4.1 Withdrawal procedures

Participants will be withdrawn from the study if:

They request withdrawal
They become ill and no longer able to participate
Researchers or professionals will withdraw participants if there are indications that this should be the case

6 DATA COLLECTION & MANAGEMENT

6.1 DATA MANAGEMENT SYSTEM

This is a qualitative intervention development study. We will collect demographic data using proformas, which will be used to describe the population using EXCEL, and qualitative data that will be managed in NVivo. As this is not a non-CTIMP, we are not collecting data to evaluate effectiveness so a CRF and managed DMS is not required. For Wave 2 we will collect data to assist us in deciding which outcome measures would be used in subsequent studies.

Information stored in EXCEL and NVivo will be managed in line with all applicable principles of medical confidentiality and data laws. The Data Controller will be the University of Dundee and the Data Custodian will be the Chief Investigator.

All data, qualitative and demographic data, will be managed in line with all applicable principles of medical confidentiality and UK law on data protection, namely, the Data Protection Act 2018, which brought UK law into line with the EU Data Protection Directive (https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted).

The CI may delegate proforma completion but is responsible for completeness, plausibility and consistency of the proforma. Any queries will be resolved by the CI or delegated member of the study team.

7 STATISTICS AND DATA ANALYSIS

7.1 SAMPLE SIZE CALCULATION

As this is an intervention development study a formal sample size calculation is not required. The intervention is being delivered to participants in order to obtain participant views so the data collected is qualitative. Forty-four participants recruited from two health board areas, will be sufficient to elicit the views of participants and guide intervention development processes that provide review and revision of the intervention. The proposed sample will be large enough for in-depth exploration of the research questions, but not so large that it prohibits time for a robust analysis to be undertaken.

7.2 PROPOSED ANALYSES

The analysis will assess the participants' experience of all aspects of the study. It will determine the appropriateness of the recruitment strategy and the design and delivery of the intervention for future feasibility and randomised controlled trials. Through consultation with the Collaborative Working group, the aim is to revise the intervention to make it acceptable for stroke survivors and ready to take to a randomised controlled trial.

Qualitative analysis of the data using thematic data analysis, managed using NVivo will inform the final amendments to the intervention and methods for implementation of the intervention in a subsequent feasibility study and RCT.

Analysis will be ongoing thematic analysis of qualitative data during Phase 2 to inform the refinement of the behaviour change intervention, and how it can be delivered.

Baseline assessment: We will describe the demographic characteristics and usual physical activity and goals for increasing levels of activity. We will also assess participants' motivation and their perceived barriers to being more active.

Interim telephone assessments: A sample of participants will be purposefully selected for disability, age and SIMD (n=7 in Wave 1, n=12 in Wave 2) to receive structured telephone interviews from the RA, using a simple proforma schedule to explore and record participants' experiences and views on how the intervention is working "in-use" for them, as messages are delivered. The interviews will be recorded and transcribed. Data will be analysed as it is

collected, by two researchers, using Framework Approach and used to inform the CWG and subsequent revisions to the intervention.

End of intervention assessment: We will assess how components of the intervention were used i.e. the extent to which: goals and action plans were set and achieved; problem solving and coping planning were practiced; and exercise, recovery activities and physical activity maintained.

During Wave 2, data will be collected at baseline and end of intervention at 12 weeks on a range of outcome measures described above. This will be done by telephone, in the case of questionnaires, and by sending and receiving the accelerometer, which we will ask people to return after 7 days of wear at the beginning and end of the study.

The purpose of this data collection is to evaluate the acceptability and feasibility of the battery of measures in preparation for a future RCT. We will collect information on completion rates and missing data, and interview data about experiences of undertaking the measures.

Although we will compute scores, we will only examine change between baseline and outcome, we will not undertake any inferential statistical analysis.

In a final interview, participants will be asked to discuss the utility and acceptability of the intervention, and how they feel it could be amended and improved. In preparation for future studies, we will also seek information about intervention feasibility and outcomes important to participants.

TRANSFER OF DATA

Data to be transferred from NHS Grampian are potential participants' contact details (the completed *(Expression of interest form)*, and the *Participant referral form* which gives information on their suitability for entry to the study and details of community rehabilitation. Therapists will be sent these forms by email using Microsoft Word's 'encrypt and password-protect' function. Passwords to open the documents will be sent in a separate email. Therapists will be asked to complete the forms and return the encrypted, password protected documents to the researcher by email.

8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

8.1 STUDY MANAGEMENT GROUP

The Core Research Team (CRT) comprises the Principal Investigator and all study co-investigators. The members have a range of expertise in designing interventions, stroke rehabilitation, health psychology, software design and trial management. The CRT will convene approximately every six weeks to review progress, adherence to the protocol and take decisions on the conduct of the study.

8.2 INSPECTION OF RECORDS

The CI, PIs and all institutions involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

9 GOOD CLINICAL PRACTICE

9.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP).

In addition to Sponsorship approval, a favourable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

9.2 CONFIDENTIALITY AND DATA PROTECTION

The CI and study staff will comply with all applicable medical confidentiality and data protection principles and laws with regard to the collection, storage, processing and disclosure of personal data.

The CI and study staff will also adhere to the NHS Scotland Code of Practice on Protecting Participant Confidentiality or equivalent.

All study records and personal data will be managed in a manner designed to maintain participant confidentiality. All records, electronic or paper, will be kept in a secure storage area with access limited to appropriate trial staff only. Computers used to collate personal data will have limited access measures via usernames and passwords.

Personal data concerning health will not be released except as necessary for research purposes including monitoring and auditing by the Sponsor, its designee or regulatory authorities providing that suitable and specific measures to safeguard the rights and interests of participants are in place.

The CI and study staff will not disclose or use for any purpose other than performance of the study, any personal data, record, or other unpublished, confidential information disclosed by those individuals for the purpose of the study. Prior written agreement from the Sponsor will be required for the disclosure of any said confidential information to other parties.

Access to collated personal data relating to participants will be restricted to the CI and appropriate delegated study staff.

Where personal data requires to be transferred, an appropriate Data Transfer Agreement will be put in place.

Published results will not contain any personal data that could allow identification of individual participants.

All evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Data will be stored in a secure locked filing cabinet within a locked room within the university, that will be allocated so the researchers can access it despite building access restrictions due to COVID-19. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor or its designee. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

9.3 INSURANCE AND INDEMNITY

The University of Dundee is the sponsor for the study.

Insurance – The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.
Tayside Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme (“CNORIS”) which covers the legal liability of Tayside in relation to the study.

Where the study involves University of Dundee staff undertaking clinical research on NHS patients, such staff will hold honorary contracts with Tayside Health Board which means they will have cover under Tayside's membership of the CNORIS scheme.

Indemnity The Sponsor provides study participants with indemnity in relation to participation in the Study but have insurance for legal liability as described above.

10 ADVERSE EVENTS

10.1 DEFINITIONS

Adverse Event (AE)	Any untoward medical occurrence in a clinical research participant which does not necessarily have a causal relationship with study participation
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life threatening • requires hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability or incapacity • is a congenital anomaly or birth defect • Or is otherwise considered serious

10.2 RECORDING AND REPORTING AE

All AEs and/or SAEs will be recorded on an AE log and will be assessed for severity by the CI or delegate. AEs/SAEs will be recorded from the time a participant consents to join the study until the participant's last study visit.

The most likely adverse event in this study is falling, as participants are stroke survivors, many of whom will have impaired mobility.

The Investigator will make a clinical judgment as to whether or not an AE is of sufficient severity to require the participant's removal from the study. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable AE. If either of these occurs, the participant should, if required, be offered an end of study assessment and be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable. SAEs will be followed up until 30 days after participant's last visit.

The CI or delegate will ask about the occurrence of AEs/SAEs and hospitalisations at every visit during the study. SAEs which are both unexpected and related to study participation will be submitted on an HRA NCTIMP Safety Report form to the REC by the CI, within 15 days of becoming aware of the SAE, and copied to the Sponsor Research Governance Office.

Worsening of the condition under study will not be classed as an AE but will be defined as an outcome. Pre-specified outcome(s) will not be classed as an AE but as an outcome. Elective admissions and hospitalisations for treatment planned prior to randomisation, where

appropriate, will not be considered as an AE. However, SAEs occurring during such hospitalisations will be recorded.

11 ANNUAL REPORTING REQUIREMENTS

Annual reporting will be conducted in compliance with TASC SOP 15: Preparing and Submitting Progress and Safety Reports in CTIMPs and Non-CTIMPs, as a condition of sponsorship and as a condition of a favourable opinion from a REC. An HRA Annual Progress Report for NCTIMPs will be prepared and submitted by the CI to REC, and copied to the Sponsor, on the anniversary date of the REC favourable opinion.

Any safety reports additional to SAE reports, for example, reports of a DMC, will be sent by the CI to REC, with a Safety Report Form, and to the Sponsor.

12 STUDY CONDUCT RESPONSIBILITIES

12.1 PROTOCOL AMENDMENTS, DEVIATIONS AND BREACHES

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor, REC and NHS R&D Office(s). Amendments to the protocol or other study docs will not be implemented without these approvals.

In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be documented and submitted to the Sponsor as a potential breach report. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP or protocol is suspected, this will be reported to the Sponsor Governance Office immediately.

12.2 STUDY RECORD RETENTION

Archiving of study documents will be for five years after the end of study.

12.3 END OF STUDY

The end of study is defined as last patient last contact (this will be the final evaluation telephone interview with the last participant). The Sponsor, CI and/or the SC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

13.1 AUTHORSHIP POLICY

Members of the Core Research Team and other personnel who have contributed to the study design, conduct or analysis, will be co-authors on the final study report and on subsequent papers for publication, as appropriate (according to the authorship criteria for manuscripts submitted for publication as defined by the International Committee of Medical Journal Editors).

13.2 PUBLICATION

The Final report will be submitted to CSO. The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

13.3 PEER REVIEW

The study was peer reviewed within the School of Health Sciences before it was submitted as a grant application. It was then peer reviewed by experts in the fields of stroke management, rehabilitation and behaviour change at the request of CSO. It was also reviewed by CSO Committee members. The study design was amended in the light of reviewers' comments prior to funding being awarded from CSO.

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15 APPENDIX 1: PHASE 1 SUMMARY PROTOCOL

Promoting physical activity and exercise after stroke using a text message intervention (Phase 1)

Study design

The intervention was developed over a period of four months using iterative co-design processes and guided by the MRC Framework for Complex Interventions (1). The Core Research Team (CRT), comprising all study investigators, worked with a Collaborative Working Group (CWG) to co-design the intervention. The CWG includes eight stroke survivors from existing PPI groups, seven therapists, eight academics with a special interest in stroke, rehabilitation, biomechanics, clinical trials and speech and language therapy and two representatives from stroke organisations i.e. Chest Heart and Stroke Scotland and the Stroke Association. The co-design team will met through videoconferencing meetings. The CWG method uses a structured decision-making matrix to guide group discussion (2).

The intervention was designed to be delivered by a series of SMS messages over 12 weeks. The messages will provide real-time support for goal setting, planning and self-monitoring of physical activities to promote recovery from stroke. The messages also aim to enhance motivation, combat the feeling of abandonment and support the uptake and maintenance of exercise and physical activity.

The intervention, to be pilot tested in the Phase 2 of the study, was created using:

- Data from systematic reviews of exercise and physical activity after stroke and SMS messaging interventions
- Data from telephone interviews with 14 stroke survivors
- The Health Action Process Approach (HAPA), the psychological model used as the theoretical basis for the intervention (3)
- Input from the CWG, that includes our stroke Patient & Public Involvement (PPI) Group

Study methods

The intervention was developed iteratively in four stages:

1. Setting the empirical and theoretical foundations of the intervention
    a. Systematic reviews on physical activity after stroke and SMS interventions
    b. Telephone interviews with stroke survivor on SMS intervention content and delivery
    c. Theoretical model underpinning the intervention
2. First Collaborative Working Group (CWG) meeting to co-design the intervention
3. Implementing recommendations from the CWG to fully develop the intervention
4. Second Collaborative Working Group meeting to review and refine the intervention
5. Review of the draft messages by stroke survivors, their family members, the CRT and selected members of the CWG

1. Setting the empirical and theoretical foundations of the intervention

Literature review

We used findings from published systematic reviews of exercise and physical activity after stroke (4, 5, 6) and existing systematic reviews and overviews of SMS messaging interventions (7, 8) to inform initial intervention development. We will also undertook a rapid evidence scan to ensure that we identified any new and salient reviews and papers relevant to SMS interventions that could inform intervention development.

Individual interviews to determine acceptable features of an SMS intervention

We conducted 14 interviews with community dwelling stroke survivors recruited via PPI groups and by therapists in Grampian and Tayside, to seek their views on the characteristics of a useful SMS intervention. Previous work with our PPI group confirmed that there is a need for an intervention at the end of the community rehabilitation period and that an SMS intervention could help to fill the gap.

Sampling and Recruitment

Between 1st October 2020 and 31st January 2021, we invited stroke survivors from rural and urban areas in Tayside and Grampian to participate in telephone interviews. All participants had access to mobile phones and had communication and cognitive abilities that enabled them to provide informed consent. We identified participants through local stroke groups and stroke exercise groups, and from a pool of people who have taken part in our previous studies and have provided consent to be contacted about studies that might be of relevance to them.

Fourteen stroke survivors, nine men and five women were recruited. Their ages ranged from 37 – 79 years (median 57.5 years). The time since stroke ranged from 4 months to 16 years. The Scottish Index of Multiple Deprivation (SIMD) scores for participants included all quintiles (number per quintile (1-5) were 6,1,2,2 and 3 respectively).

Data Collection and analysis

We were aware that participants would find it difficult to imagine how a text messaging intervention might look and work. Therefore, informed by the ongoing review and our previous SMS research, developed illustrative messages. These were sent out by email or post before the interview. We used the example to enable us to explore participants' opinions on acceptability and feasibility of SMS interventions. We sought their views on intervention components including the frequency and tone of texts, and possible links to web resources. Topics were iteratively adjusted based on emerging findings from the review and from preceding interviews. Interviews were audio-recorded and transcribed. Field notes will be taken to provide context. Data were analysed by two researchers using Framework Analysis (9).

Theoretical Mapping

The Health Action Process Approach (HAPA) was used as the theoretical basis for the intervention (3). The HAPA regards behaviour change as a process involving two phases: a motivational phase where the intention to be physically active or exercise is influenced by perceptions of risk, outcome expectancies, action self-efficacy, and a volitional phase where intentions are translated into behaviour through action planning, coping planning, and self-efficacy to maintain behavioural change.

HAPA is widely used for PA promotion and formed the theoretical basis for our previous SMS studies (10, 11). Drawing on our systematic reviews (5) and the qualitative data from this and previous studies (12), we systematically mapped known influences on PA and exercise after stroke to the HAPA, to identify relevant behaviour change techniques to support achievement of PA and post-rehabilitation goals.

Specifically, we will createda framework which enabled us to match themes and sub-themes from current and previous qualitative work to each of the constructs of the HAPA. We identified relevant behaviour change techniques that were subsequently translated into a sequence of SMS messages. We complemented HAPA with a behaviour change maintenance framework developed by a co-applicant (SD) (13) to guide incorporation of behaviour change techniques for long-term behaviour change.

CWG Meeting: co-designing the intervention with stroke survivors and other stakeholders

We convened two meetings of the CWG using Microsoft Teams (November and December 2020)..

Note: The CWG is viewed by TASC as PPI and does not therefore need ethical approval (see attached email). We provide information here only to explain the Phase 1 process of intervention development.

2. The CWG team met to review and discuss the findings from the existing literature reviews and interviews in order to make decisions about intervention design. The CWG method uses a structured decision-making matrix to guide discussion (2). The meeting was chaired by the PI and the CWG and CRT worked together work to reflect on the findings and agree on core intervention components. **Development of the intervention**

The CRT implemented the action plan agreed at the CWG meeting to operationalise core intervention elements and developed a intervention logic model and defined intervention components.

The SMS messages have been developed to be delivered in phase 2 via TextApp, a software tool developed by co-applicant Jones, and used in a number of SMS behaviour change intervention studies (10, 11). Messages will be sent by an automated computer system which will be programmed to send out text messages to participants' mobile phones in a predetermined sequence. The exchange of text messages with the participants will be via a secure server based within the Health Informatics Centre at the University of Dundee. The message schedule and any personalisation will be programmed into the TextApp delivery system which also handles replies and delivery monitoring.

3. Second Collaborative Working Group to review and refine the intervention

The second CWG meeting was used to review and revise the content of the text messages

The CRT actioned the recommendations made by the CWG to finalise the intervention to be tested in Phase 2 of the study.

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