

Timing of text message prompts to increase trial participant response to postal questionnaires in UK-FROST

Submission date 15/07/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/08/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In studies, an important and low cost way of getting health information directly from patients is to send questionnaires by post. However when these questionnaires are not completed and returned by patients, it can mean the study has less information than it needs to make useful and meaningful conclusions. It is important to find new ways to improve the return of postal questionnaires, and the best way of testing these strategies is in real life studies. Text messages are a simple, cheap and widely used form of communication. They have also been shown to improve the numbers of patients who take part in studies. However it is unclear when the most effective time to send a message for encouraging people to return postal questionnaires. The researchers for this study have recently done trials to compare the timing of text message reminders sent on the day the questionnaires were posted to patients (called 'pre-notification'); four days after questionnaires were sent (called 'post-notification'); or no text message reminders. The results did not reveal which was better, so it is important to get further evidence by doing more research to clarify previous findings.

Who can participate?

Participants of the UK-FROST trial, which looks at the effectiveness of three treatments for frozen shoulder. More information for this study can be seen here: ISRCTN48804508

What does the study involve?

All participants are sent a letter with a patient questionnaire 3 months after their participation in the UK FROST trial. Participants are randomly allocated to one of two groups. Those in group 1 receive text messages on the day the questionnaire is posted out, with the message "UK FROST Trial: You will receive a questionnaire in the post in a few days. Your answers are important; so please help by returning it as soon as you can. Thanks." Those in group 2 receive a text message 4 days after the questionnaire is posted out with the message "UK FROST Trial: You should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks". Data is then collected as to how many participants

return a completed questionnaire, how long it takes them to complete the questionnaire and how many patients need to be sent at least one reminder before they send back the questionnaire.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The James Cook University Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2014 to June 2019

Who is funding the study?
Health Technology Assessment Programme (NIHR)

Who is the main contact?
Dr Stephen Brealey
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Timing of text message prompts to increase trial participant response to postal questionnaires in UK-FROST: an embedded retention trial

Study objectives

To evaluate whether SMS text messages sent as pre- or post-notification reminders improve questionnaire response rates in the United Kingdom Frozen Shoulder Trial (UK FROST) host-trial during the 3 month follow-up of participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North East (Newcastle & North Tyneside 2) Ethics Committee, 18/11/2014, ref: 14/NE/1176. Substantial Amendment 2 – REC gave favourable opinion for this text message study on 24/05/2016.

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Frozen shoulder (adhesive capsulitis)

Interventions

Text messages will be sent in addition to the initial mailing out of a letter with the patient questionnaire at 3 months follow-up.

Intervention group: In the pre-notification group, text messages will be sent on the day the questionnaires are posted to participants. Content of the message will read: 'UK FROST Trial: You will receive a questionnaire in the post in a few days. Your answers are important; so please help by returning it as soon as you can. Thanks.'

Control group: In the post-notification group, messages will be sent four days after questionnaires are sent. 'UK FROST Trial: You should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks'

Intervention Type

Behavioural

Primary outcome measure

The proportion of participants who return a valid questionnaire at the three month follow-up.

We define a valid questionnaire as one containing a completed response for at least the primary outcome questionnaire (The Oxford Shoulder Score) at the three month follow-up.

Secondary outcome measures

1. Time to questionnaire return (number of days between the questionnaire being mailed out to participants and it being recorded as returned)
2. The proportion of patients requiring at least one return reminder notice (a letter at 2 and 4 weeks and a telephone call 6 weeks following non--return)

Overall study start date

01/10/2014

Completion date

30/06/2019

Eligibility

Key inclusion criteria

1. Participants enrolled into the UK FROST trial
2. Access to a mobile telephone
3. Provided consent to be contacted by text message

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Total final enrolment

269

Key exclusion criteria

Patients not consenting to be contacted on their mobile telephone

Date of first enrolment

18/07/2016

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The James Cook University Hospital

United Kingdom

Middlesbrough

United Kingdom

TS4 3RT

Sponsor information

Organisation

South Tees NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02js17r36>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The embedded study will be registered in the SWAT database, encouraging others to adopt or adapt this in their own trials. We will publish our findings in a peer reviewed journal and present findings at conferences.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2020	02/06/2020	Yes	No
Protocol file			12/08/2022	No	No
HRA research summary			28/06/2023	No	No