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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

Registration date
22/07/2016

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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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

HTA 13/26/01

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
Research and Development Department
Academic Centre
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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