Contacting by telephone prior to dispatching postal questionnaires increases response rates in a senescent and frail patient population

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/05/2013		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/06/2014	Completed	[X] Results		
Last Edited 23/09/2016	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Recent studies do no not provide sufficient information on how to increase response rates in patients. This study is currently in the middle of a large data-collection phase and over the next year will send postal 12-month follow-up questionnaires to patients who have been discharged from the Akershus University Hospitals stroke unit (SU). These patients have already received 3-month follow-up questionnaires. Several patients have already been pre-selected to be contacted by telephone; those are the patients for whom we have available a primary care-giver (relative or other), and who are either above 80 years of age, or who were discharged to some address other than their home address (i.e. a rehabilitation facility). In this study, we aim to find out if contacting the remaining patients by telephone before sending out the questionnaires can increase response rates.

Who can participate?

Patients who have not previously been contacted or who did not fill in or receive the questionnaire can take part.

What does the study involve?

The patients are randomly allocated to one of two groups. The intervention group will be precontacted by telephone about 1 week before we mail them the questionnaire; the control group patients will simply receive a questionnaire by mail without being pre-contacted. All patients will receive a 12-month follow-up questionnaire by mail. The intervention group patients will be contacted by telephone before shipment.

What are the possible benefits and risks of participating? There are no benefits or risks for the participants.

Where is the study run from?

Akershus University Hospitals Health Services Research Center (HØKH), Norway.

When is study starting and how long is it expected to run for? The study started in June 2013 and ended in April 2014.

Who is funding the study? The Research Council of Norway (Norway).

Who is the main contact? Dr Mathias Barra mathias.barra@ahus.no

Contact information

Type(s)

Scientific

Contact name

Dr Mathias Barra

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Contacting by telephone prior to dispatching postal questionnaires increases response rates in a senescent and frail patient population: an open randomized controlled trial

Study objectives

To determine whether contacting by telephone prior to dispatching postal questionnaires can increase response rates in a senescent and frail patient population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not required: The NOR-SPOT project has been submitted to a regional ethics committee for medical research, and exempted from evaluation because the study hypotheses were not directly related to health and illness.

Under Norwegian law it is therefore sufficient that the project, as it has been, is approved by the hospital's internal privacy ombudsman. Randi Otterstad (randi.otterstad@ahus.no); Ref: 11.076.

Study design

Interventional open randomized controlled trial with two study branches

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Response rate to postal questionnarie targeting stroke patients

Interventions

The telephone pre-contact intervention will be performed according to the following procedure:

1. Three attempts will be made to contact the subjects on their mobile phone (land-line when no mobile-number is available). If contact is established during one of these three attempts, or on a call-back the caller will aim at achieving what we call as an informal consent to shipping. This means that the caller will aim at having the participant agree to receive the questionnaire for

their review.

- 2. The caller may answer questions about the survey, but should remain neutral
- 3. Any house-hold member can act as proxy for the participant e.g., a spouse or other family member answering the phone
- 4. Where a prior written consent to participation (given at the SU) exists, the caller reminds the participant of this fact. However, the caller must not induce guilt for not having responded to the 3-month shipment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Response rate: the total number of responders who responded within 45 days of shipping out.

Secondary outcome measures

Final response rate: the total number of responders who responded after 365 days.

The intervention (pre-contact by telephone) will be undertaken between June 1st 2013 and April 1st 2014, but that the second outcome "response rates within 356 days" will (necessarily) be recorded on April 1st 2015.

Overall study start date

01/06/2013

Completion date

01/04/2015

Eligibility

Key inclusion criteria

We will include NOR-SPOT patients who:

- 1. Have not previously been contacted
- 2. Have not returned the 3-month questionnaire or did not receive the questionnaire
- 3. Who are not pre-selected for pre-contact: viz. those who were discharged to their own home, under the age of 80, or those with a spouse or other relative living at their home address
- 4. Has a phone number for contact
- 5. Have a confirmed stroke diagnosis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

400

Key exclusion criteria

Patients will be excluded when it is discovered that the patient is no longer alive within 7 days after dispatch of the questionnaire. This goes for participants both in the control and the intervention groups.

Date of first enrolment

01/06/2013

Date of final enrolment

01/04/2014

Locations

Countries of recruitment

Norway

Study participating centre Sykehusveien 25

Lørenskog Norway 1478

Sponsor information

Organisation

Akershus University Hospital (Norway)

Sponsor details

Sykehusveien 25 Lørenskog Norway 1478

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Sponsor type

Hospital/treatment centre

ROR

https://ror.org/0331wat71

Funder(s)

Funder type

Government

Funder Name

Norges Forskningsråd

Alternative Name(s)

Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Results and Publications

Publication and dissemination plan

We are planning to publish the results in April 2015

Intention to publish date

01/04/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2016		Yes	No