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Using GPS trackers in dementia patients to improve quality of life

Submission date
26/04/2022

Recruitment status
No longer recruiting

Registration date
09/05/2022

Overall study status
Completed

Last Edited
21/12/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In 2018 alone, 189 people with dementia were subject to missing person searches in South Yorkshire, costing £9000 per search. Currently, some families have reported locking their family members in the house to avoid wandering. This might have negative consequences on the physical and mental health of the person and potentially fatal consequences if there were a fire. Wandering behaviour often results in people being institutionalized, limiting a person's freedom, and potentially reducing mental and physical health at a high cost. From a safeguarding perspective, wandering behaviour can lead to considerable harm and death if a lost person is not found as soon as possible, and several serious incidents have occurred across West Yorkshire in recent years.
Global Positioning Satellite (GPS) technologies have continued to improve and now offer a compact and reliable tool to enable the location of people when lost. This may reduce emotional distress and the risk of physical harm. These tools may also allow family members to find relatives, reducing the burden on police and rescue services. Significantly, these tools may prolong the time people with dementia are able to live independently in the community, improving their quality of life and reducing the burden on the care sector.
Despite the potential benefits of GPS, research in the UK is very limited. This pilot study investigates whether using GPS trackers can help people with dementia or mild cognitive impairment live a better quality of life for longer in their own homes by mitigating the risks of harm from wandering behaviour.

Who can participate?
Adult members in the community who live in their own homes or supported accommodation and have a diagnosis of dementia or memory impairment. The individual must have a carer who is either a family member or friend but not any member of a paid care team.

What does the study involve?
Individuals will be given a GPS tracker with software to track the device and enough data to last for 6 months of the study. The research team will ask participants to sign an informed consent and socio-demographic information will be collected through a brief interview. Participants will fill out a questionnaire measuring on carer's burden, wearer's quality of life, and wearer's wandering behaviour before the study starts. Participants will fill out the same questionnaire at

follow-up. The carers of participants will also be invited to a focus group of carers and asked whether they would like to be interviewed by the study team about their experiences. There will be monthly checks by the research team to ensure participants are getting on well with the device.

What are the possible benefits and risks of participating?
There will be reduced risk associated with wandering behaviour, participants will experience greater independence thereby increasing their quality of life. It will reduce the burden of care for people with memory impairment and give reassurance to family members; participants can stay with family for longer, reducing the pressure on healthcare services. Participating in this study is low risk and potentially risk-reducing. However, using the GPS trackers may give relatives false reassurance about the safety of their relatives, and they could still struggle to find the relative if they wander even with the GPS tracker.

Where is the study run from?
University of Huddersfield and South West Yorkshire Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to January 2023

Who is funding the study?
NHS Research Capability Funding (UK)

Who is the main contact?
Dr Mike Doyle
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297216

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 297216

Study information

Scientific Title
A longitudinal pilot study to investigate the use of GPS trackers in dementia patients who are at risk of wandering

Acronym
GPS Study

Study objectives
1. GPS trackers will decrease the incidence of harm from wandering for people diagnosed with dementia or memory impairment
2. Wearing a GPS tracker will reduce the use of the police to help locate the individuals
3. Wearing a GPS tracker will improve the quality of life of both the individual and their carers
4. People diagnosed with dementia or memory impairment, and their carers will find GPS trackers useable and acceptable

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2021, North West – Greater Manchester (GM) South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048014, +44 (0) 2071048221, +44 (0)2071048143; gmsouth.rec@hra.nhs.uk), ref: 21/NW/0290

Study design
Pilot non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)

Quality of life

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Quality of life of people diagnosed with dementia or memory impairment who are at risk of wandering or getting lost

Interventions
This pilot study was developed as a collaboration between Southwest Yorkshire Partnership NHS Trust (SWYPT), Primary Care colleagues, South & West Yorkshire Police and the University of Huddersfield. The research will evaluate the feasibility, acceptability and effectiveness of a GPS tracking unit, which will alert family or next of kin if the patient begins to wander outside of a predesignated area using a research design based on a similar Canadian study.

In 2018 alone, 189 people with dementia were subject to missing person searches in South Yorkshire, costing £9000 per search (unpublished). Currently, some families have reported locking their family members in the house to avoid wandering. This might have negative consequences on the physical and mental health of the person and potentially fatal consequences if there were a fire.
Wandering behaviour often results in people being institutionalized, limiting a person's freedom, potentially resulting in a reduction in both mental and physical health and at a significant cost.

From a safeguarding perspective, wandering behaviour can lead to significant harm and death if a lost person is not found ASAP, and several serious incidents have occurred across West Yorkshire in recent years.

Global Positioning Satellite (GPS) technologies have continued to improve and now offer a compact and reliable tool to enable the location of people when lost. This may reduce emotional distress and the risk of physical harm. These tools may also allow family members to find relatives, reducing the burden on police and rescue services. Significantly, these tools may prolong the time people with dementia are able to live independently in the community, improving their quality of life and reducing the burden on the care sector.
Despite the potential benefits of GPS, research in the UK is very limited.

Methodology
The trial is a 6-month pilot study, which will inform a future larger-scale piece of work, possibly with a control group. This trial will not have a control group – just an intervention group, though some comparisons may be able to be drawn with data from wandering with the current standard care in place.

The trial design is a pre and post comparison recruiting up to 50 dyads of patients and carers (comprising of an individual with dementia/mild cognitive impairment and a nominated caregiver). Individuals will have been assessed by the Wakefield or Barnsley Memory services or identified by police as being at risk of harm through wandering, either at initial or subsequent assessments.

The dyads will be given a GPS tracker with a software package that can locate the tracking device and enough data to last for a 6-month trial period.

All participants will be required to provide informed consent by filling out a consent form.

Before starting the study, baseline measures will be taken using questionnaires and a brief initial interview. These questionnaires will then be repeated at the end of the six-month study period, and the data will be collated with interview and focus group data. The primary outcome measure will be to assess whether or not they end up having to go into a 24-hour care facility (such as a hospital, nursing home or residential home). The researchers will also be looking at other 'hard' outcome measures such as incidences of wandering behaviour where the trackers have had to be used, whether the police have been required to assist with the search, and any hospital admissions associated with a wandering episode.

In addition to our assessments at baseline and at 6 months, the police are also planning on collecting information at monthly intervals or in the case of any instances where the tracking device has needed to be used to locate a relative.

Assessments at baseline and 6 months follow-up

Demographic and diagnostic information will be recorded at baseline for each patient based on a brief interview with the patient and/or collateral interview with the carer, and the following questionnaires will be administered:
1. Zarit-Burden Interview – An extensively used self-reported tool to measure the extent to which a caregiver perceives his or her level of burden as a result of caring for a person (baseline and follow-up)
2. Cornell-Brown Quality of Life Index – A self-reported tool to measure perceived quality of life specifically designed for patients with dementia and cognitive impairment (baseline and follow-up)
3. Algase Wandering Scale – A 28-point questionnaire based on five dimensions of wandering. This tool is designed to measure wandering behaviours in people with cognitive impairment (baseline and follow-up)
4. University of Alberta GPS Usability Questionnaire (Patient) – A questionnaire designed to measure the useability and impact of a GPS tracking device on a person with dementia who wanders (follow-up only)
5. University of Alberta GPS Usability Questionnaire (Carer) – A questionnaire designed to measure the useability and impact of the GPS unit on the daily life of the person they're caring for (follow-up only)

The researchers will endeavour to keep loss to follow up to a minimum by maintaining a good working relationship with the dyads and making monthly contact during the study period to offer support. The research team will follow up with non-responders to questionnaires.
Focus group interviews will be guided by an interview guide to meet the study's objective.

Analysis
The researchers will analyse a combination of quantitative and more qualitative outcome measures, such as quality of life, to see if there was any change during the duration of the study.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

The number of participants who need admission to a 24-hour care facility such as a hospital, nursing home or residential home, measured using monthly check-in calls and/or post-trial supportive contact for 6 months

Secondary outcome measures
1. Number of times the GPS tracker has been used to retrieve the wearer, measured by liaising with individual dyads during monthly and post-trial supportive contacts for 6 months
2. Number of hospital admissions as a result of wandering, measured using the Revised Algase wandering scale at baseline (within 2 weeks before joining the study) and follow-up (end of 6 months in the study)
3. Number of times the police have needed to be contacted due to an incidence of wandering, measured using the Revised Algase wandering scale at baseline and follow-up, and review of police records
3. Quality of life of both wearer and carer, measured using the Zarit Burden interview questionnaire and Cornell-Brown Quality of life index at baseline (before joining the study) and follow-up (end of 6 months of joining the study)
4. Usability and acceptability of the product measured using the UoAlberta GPS useability questionnaire (Wearer & Carer) at follow up (end of 6 months of study)

Overall study start date
10/01/2022

Completion date
31/01/2023

Eligibility

Key inclusion criteria
1. Individuals must have a designated family member/close friend who will supervise the use of the device including being able to access and use the accompanying software.
2. Nominated friend must not be any member of paid care staff
3. Participants must live in an area served by South West Yorkshire Partnership NHS Trust memory services
4. Individuals must be either living in their own homes or in supported accommodation

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
45

Key exclusion criteria
1. If an individual does not have a close family member identified at the outset, he/she will be excluded from the study
2. If participants move out of this area to a different locality before the end of six months duration of the study, they will cease to be part of the study
3. If individuals make a permanent move to a 24-hour residential care setting, they will cease to be part of the study

Date of first enrolment
28/01/2022

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Fieldhead
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Sponsor information

Organisation
South West Yorkshire Partnership NHS Foundation Trust

Sponsor details
c/o Dr Wajid Khan
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United Kingdom
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Sponsor type
Hospital/treatment centre

Website
https://www.southwestyorkshire.nhs.uk/contact-us/

ROR
https://ror.org/02m7qex15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Research Capability Funding (RCF) (SWYPT)

Results and Publications

Publication and dissemination plan
The findings of this pilot study will be shared across Yorkshire and Humber partners including the NHS, Social Care, Police, Yorkshire Ambulance Service and care providers from the voluntary and private sectors. The findings of this study will also be submitted for publication in high-impact journals

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Data handling will be undertaken by Good Clinical Practice (GCP)-trained staff at South West Yorkshire Partnership NHS Foundation Trust. All data will be stored securely using password-protected NHS secured laptops. Data will be stored on secure NHS databases. Paper consent forms will be stored securely in a locked cabinet within the R&D department at South West Yorkshire Partnership NHS Foundation Trust. Trial data may be accessed by those connected to the study team on application to and at the discretion of the Chief Investigator. The type of data would be anonymous datasets, qualitative and quantitative data, available at the end of the trial for 5 years, all requests would be reviewed to assess if appropriate on an individual basis on receipt by the Research Office in collaboration with the Chief Investigator, following the review any participant-level data to be shared would be via a suitable and secure medium following sponsor guidance. Participants have been consented into the study and are aware that data

collected will be analysed and may be used to inform future research. Requests to be made via Research & Development, South West Yorkshire Partnership NHS Foundation Trust (research@swyt.nhs.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	02/12/2021	03/05/2022	No	Yes
Participant information sheet	version 3	02/12/2021	03/05/2022	No	Yes
Protocol file	version 2		03/05/2022	No	No
HRA research summary			28/06/2023	No	No