South West Yorkshire Partnership
NHS Foundation Trust

Using GPS Trackers in dementia patients to improve quality of life

Study Protocol V2

1. Background and Rationale

Dementia is a disability that can significantly affect patients' cognition and navigation[1]. It is estimated that 40% of people diagnosed with dementia will get lost, with 5% of these people getting lost repeatedly[2]. When patients get lost, this causes significant emotional distress and can result in physical harm or death. This is also associated with a significant burden and cause of anxiety for family members trying to support these patients. This is also a significant burden to both the police, primary care and wider NHS.

In 2018 alone, in South Yorkshire 189 people with dementia were subject to missing persons searches costing on average £9000 per search (unpublished). Currently, some families have reported locking their family members in the house to avoid wandering[1]. This may have negative consequences on the physical and mental health of the person as well as 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. These patients seek help through a variety of services including their GP or primary care practitioner, mental health services, Police, Ambulance service or A&E. This may represent multiple clinical appointments and input from primary care specialists. These patients are subsequently referred to specialist secondary care clinicians through specialist memory services, where they are seen by trained specialists. This can be a protracted and complex process to both primary and secondary care services. From a safeguarding perspective, wandering behaviour can lead to significant harm and death if person who is lost 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[3]. These tools may also allow family members to find relatives, thereby reducing burden on police and rescue services. Importantly, these tools may prolong the time people with dementia are able to live independently in the community, improving their quality of life and reducing burden on the care sector. Indeed, a small study in Canada demonstrated that offering GPS trackers to patients with dementia reduced carer anxiety and burden, improved the quality of life of

[1] Bartlett, R. and Topo, P. (2019). Using GPS technologies with people with dementia: A synthesising review and recommendations for future practice. *Tidsskrift for omsorgsforskning*, 5 (3), 84-94.
[2] Carr, D. et al. (2010). Silver alerts and the problem of missing adults with dementia. *Gerontologist.* 50(2): 149-157.
[3] Bartlett, R. and Brannelly, T. (2019). On being outdoors: How people with dementia experience and deal with vulnerabilities. *Social Science and Medicine.* Epub: 235 (August), 112336

both patients and their family members and reduced the search time for individuals when missing[3]. Despite the potential benefits of GPS, research in the UK is very limited.

This pilot study has been developed as a collaboration between South West Yorkshire Partnership NHS Trust (SWYPT), Primary Care colleagues, South & West Yorkshire Police and the University of Huddersfield. It 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 similar Canadian study[4].

2. Trial Objectives and Design

The purpose of this study is to investigate whether using GPS trackers can help people with dementia or mild cognitive impairment to live a better quality of life for longer in their own homes by mitigating the risks of harm from wandering behaviour.

The design is to recruit up to 50 'dyads' (comprising of an individual with dementia/mild cognitive impairment and a nominated caregiver) and give them a GPS tracker with a software package that can locate the tracking device. We will follow up dyads for six months with a primary outcome of assessing whether or not they end up having to go into a 24 hour care facility (such as a hospital, nursing home or residential home). We 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 search, and any hospital admissions associated with a wandering episode.

More qualitative outcome measures will include quality of life rating scales, usability of the technology, and the subjective burden of getting lost, on both participants in the dyad.

2.1 Recruitment

We will recruit individuals with a diagnosis of dementia or mild cognitive impairment who are under the Wakefield and Barnsley Memory services. Individuals will have been assessed by our service as being at risk of harm through wandering, either at initial or subsequent assessments.

These patients are typically invited to fill out the 'Herbert Protocol' with their families, a document with key information about them, which goes to the police and is designed to try and aid with a timely recovery if they were to get lost. We already have a known group of patients who we have deemed at risk of harm through wandering and therefore will look to recruit from this group of patients.

2.2 Inclusion / exclusion

Individuals must have a designated family member/close friend who will supervise use of the device including being able to access and use the accompanying software. This should not be any sort of paid member of care staff. There is a risk that a participant could initially have capacity to consent to being involved in this study, then lose the capacity during the study period. The protocol for this is covered in the paragraph 2.3. Due to the need to then seek consent from a next of kin/family member, if a

[4] Lili Liu, Antonio Miguel Cruz, Tracy Ruptash, Shannon Barnard & Don Juzwishin (2017). Acceptance of Global Positioning System (GPS) Technology Among Dementia Clients and Family Caregivers, Journal of Technology in Human Services, DOI: 10.1080/15228835.2016.1266724

potential participant does not have a close family member identified at the outset, they will not be included in the study.

For this pilot study, participants must live within the Barnsley or Wakefield areas, served by Barnsley or Wakefield NHS memory services. If they move out of this area to a different locality before end of six months duration of the study, they will cease to be part of the study.

Individuals must be either living in their own homes or in supported accommodation. If they make a permanent move to a 24 hour residential care setting, then this will be considered an end point to their involvement in the study as the tracker will no longer be necessary.

2.3 Consent

If the individual who is to be given the GPS tracker has capacity to consent to being involved in this study, we will seek their consent. All prospective individuals will have their capacity assessed.

In the event that they do not have capacity, which we envisage will occur frequently, we will seek input from their close family and/or friends to gain an insight into what the individual may have wanted based on their prior wishes and views. We will work in partnership with the individual and their carers to weight up the benefits to the individual and proportionality of the intervention balanced against the risks, which are low.

If the potential participant is found to not have capacity then consent to participate in this study will be sought from the next of kin/an appropriate family member.

In the case that a participant has capacity to consent to the study initially, and then loses it during the course of the study period, the same process will then begin with regards to consulting family members/next of kin and, if appropriate, seeking consent on their behalf instead. If consent is not obtained then the individual's participation in the study will cease immediately.

2.4 Risks, burdens and benefits

The aim of this intervention is to try and decrease the risk of harm to an individual with dementia or mild cognitive impairment through wandering. We regard enrolment in this study as a low risk measure for the dyad, and potentially a risk reducing measure.

One potential risk is that using the GPS trackers may give relatives false reassurance about the safety of their relatives, and that they could still struggle to find the relative if they wander even with the GPS tracker. Due to the accuracy of the GPS trackers, we feel that this is unlikely. Device failure is always a possibility however.

Other risks include wandering where the individual has not got the GPS tracker on them. However, this will not be an extra risk introduced by the study. Also, failure for the caregiver to be able to understand and use the software may be a risk. We will mitigate the risk of not understanding the software by giving a demonstration, providing clear guidance and offering a regular point of contact if carers require assistance.

Participants will be followed up with questionnaires at the start of the study and at the end. We will also ask for data to be provided about how much the tracker/software has been used, and the

consequences (if any) of any wandering behaviours. The carers of participants will also be invited to a focus group of carers and be asked whether they would like to be interviewed by the study team about their experiences.

2.5 Confidentiality

One issue might be people's concerns with whether or not the police will have access to the GPS tracking data. This will not happen unless the police are asked by relatives to provide assistance with locating the individual.

The caregiver/individual dyad will have sole control of the software that accesses the GPS tracking data. They will be advised that in the event of the individual wandering where they are not able to locate them on their own (either using the tracking software or not) then they should call the police in the same way they would if they were not part of this study). The police will ask the dyad whether they may have access to the GPS tracking software in order to aid their search. If this occurs there will not be an obligation for the dyad to share this information with the police.

We do not foresee any conflicts of interest between the duty of care of those clinicians involved in this project and the outcome of the project.

At the end of the study, results will be fed back to participants.

3. Trial hypotheses and objectives

People who have been diagnosed with a dementia or mild cognitive impairment can sometimes come to harm through wandering. They can get lost and can sometimes put themselves in great danger as a result. Wandering behaviour can also be a key factor in necessitating transfer to a 24 hour care facility.

This study aims to explore ways that the harm caused by wandering behaviour can be reduced. It aims to do this by giving GPS tracker devices and accompanying software to individuals and their carers so that if the individual with dementia or mild cognitive impairment wanders, they can be easily and safely found.

The objectives of this study are to investigate whether the trackers

- decrease the incidence of harm that can come from wandering,
- prolong independence in the individual's own home,
- reduce the use of the police to help locate the individuals.
- improve the quality of life of both the individual and their carers.
- are usable and acceptable.

3.1 Trial Design

The trial is a six-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. Questionnaires will be carried out at baseline, then 6 months follow-up. We will also collect data on whether there has been any need to move the individual to a 24 hour care setting, how often the tracker has needed to be used to locate the individual, and whether they have come to any harm through wandering whilst wearing the tracker – e.g. needing general hospital admission or police involvement.

Follow-up data will also be collected after six-month trial period through focus groups with carers who participated and staff who were in contact with the dyads during trial period

4. Ethical considerations

Some of our participants will not have the capacity to be able to consent to this study. In that circumstance their prior wishes will be taken into account through liaison with their nearest relatives. GPS tracking data is by its nature, personal. Only the relative and the wearer of the device will have access to the tracking software. Although the police are providing some funding for the devices, they will not have any access over them and are essentially 'gifting' these devices to the participants. The police retain no ownership over them.

5. Outcome measures

5.1 Primary outcome measure

The primary outcome measure is the number of participants who need admission to a 24 hour care facility such as a hospital, nursing home or residential home.

5.2 Secondary outcome measures

The secondary outcome measures are:

--Number of times GPS tracker has been used to retrieve wearer

--Number of hospital admissions as a result of wandering

--Number of times the police have needed to be contacted due to an incidence of wandering

--Quality of life of both wearer and carer

--Usability of product

6. Participant Entry

6.1 Screening for eligibility and preliminary information visit

Potential participants will be identified from the caseload of the Barnsley and Wakefield Memory services. A list of patients who have diagnoses of dementia or a mild cognitive impairment will be selected and those who are at a risk of harm through wandering selected. Such patients are usually already known to the team, and risk assessments for this are routinely carried out when people are initially assessed, diagnosed, and followed up. The consent to contact each participant will be sought

by clinicians currently involved in the potential participants care. The consent to take part in the study will be sought and gained by the local trust research team.

6.2 Further information and consent visit

Each potential participant approached will be noted within their clinical records by the clinician involved in their care. If an individual does not wish to take part, this will be noted in their medical records. They will not be contacted by the trust research team and invited to take part in research.

Consenting by the research team will be face-to-face if safe to do so but could be done remotely over the phone or videocall.

7. Intervention and Follow-up Procedures

7.1 Trial intervention

The intervention will be giving participants a GPS tracker with accompanying software. Enough data will be given to last for the 6 month trial period.

Before starting the study, baseline measures will be taken using questionnaires and brief initial interview. These questionnaires will then be repeated at the end of the six-month study period and the data collated with interview and focus group data.

7.2 Other treatments and interventions

In addition to our assessments at baseline and at six 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.

7.3 Assessments at baseline and six months follow-up

Demographic and diagnostic information will be recorded at baseline for each patient based on brief interview with patient and/or collateral interview with carer and the following questionnaires will be administered:

- Zarit-Burden Interview – An extensively used self-reported tool to measure to measure the extent to which a caregiver perceives his or her level of burden as a result of caring for a person[5].
- 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[6].

[5] Zarit SH, Reever KE, Bach-Peterson J. (1980). Relatives of the impaired elderly: correlates of feelings of burden. Gerontologist.20(6):649-55. doi: 10.1093/geront/20.6.649. PubMed PMID: 7203086.
[6] Ready RE, Ott BR, Grace J, Fernandez I. (2002). The Cornell-Brown Scale for Quality of Life in dementia. Alzheimer Dis Assoc Disord. 16(2):109-15. doi: 10.1097/00002093-200204000-00008. PubMed PMID: 12040306.

- 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[7].
- University of Alberta GPS Useability Questionnaire (Patient) – A questionnaire designed to measure the useability and impact of a GPS tracking device on person with dementia who wander's life[8].
- University of Alberta GPS Useability 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[8].

NB- Every effort will be made to elicit the patients views and feedback. However, it is acknowledged that some patients in the study might not be able to fully complete the questionnaires and therefore only collateral carer information would be available.

Schedule of Questionnaires

Baseline Questionnaire	**What it measures**	**Follow-up Questionnaire**	**What it measures**
Zarit Burden Interview	Carer burden	Zarit Burden Index	Carer burden
Cornell-Brown QoL Index	Patient with dementia QoL	Cornell-Brown QoL Index	Patient with dementia QoL
Algase Wandering Scale	Symptoms/severity of wandering	Algase Wandering Scale	Symptoms/severity of wandering
		UoAlberta GPS Useability (Patient)	Useability of GPS trackers (patient perspective)
		UoAlberta GPS Useability (Caregiver)	Useability of GPS trackers (carer perspective)

Additional Follow Up measures	**How will this be measured?**
1) Need to transfer individual to a hospital, residential/care home placement	Liaison with carer on whether or not the individual 1) ended up in permanent residential or nursing care as a direct or partial result of their wandering behaviour, and/or 2) was admitted to hospital.
2) Police call outs needed to help locate the individual	Review of police records.
3) Amount of times the app was used to assist with recovery of an individual a. Subset of this question could include time taken to find relative after having used the app	Liaison with the individual/caregiver dyad during post-trial supportive contact.

7.4 Minimising loss to follow-up

[7] Algase DL, Beattie ER, Bogue EL, Yao L. (2001). The Algase Wandering Scale: initial psychometrics of a new caregiver reporting tool. Am J Alzheimers Dis Other Demen. 16(3):141-52. doi: 10.1177/153331750101600301. PubMed PMID: 11398562.

[8] Juzwishin D, Raadik-Ruptash T, Barnard S, Cruz A. (2015). Usability of locator technology among home care clients at risk for wandering. Alberta Health Services: University of Alberta.

We will endeavour to keep loss to follow up to a minimum by maintaining a good working relationship with the dyads, making monthly contact during study period to offer support. Non responders to questionnaires will be followed up by the research team.

7.5 Expected Duration of Trial

The expected duration of the trial will be a six-month follow up for each participant, but 12 months in total for pre and post data collection and analyses.

8. Safety Monitoring Procedures

We do not envisage any extra risk associated with being involved in this study. The intervention itself is a risk management strategy to mitigate risks. Any issues with the functionality of the devices can be addressed by the product support teams.

All patients will continue to be managed as per trust clinical guidelines for anyone under Memory team services. This includes crisis numbers to call in and out of hours.

9. Sample Size, Statistics and Data Monitoring Procedures

The sample size has been decided to enable a pilot of the use of tracker devices ahead of future larger study

All statistical analysis will be carried out under the supervision of the SWYPT research and development team and University of Huddersfield partners. Similarly, the data monitoring procedures of the trust research department will be followed at all times.

9.1 Sample Size

We will aim to recruit 25-50 dyads. This should yield enough data with which to base a larger study on with a control group. This initial study is considered a pilot, hence the small sample size.

9.2 Analysis

We 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.

10. Organisation

This is a collaborative study between South Yorkshire Police, South West Yorkshire Hospitals NHS Foundation Trust, West Yorkshire Police, and the University of Huddersfield

10.1 Local Principal Investigator

Dr David Bishop and Prof Mike Doyle

10.2 Local Study Coordinators

Dr Arron Peace and Prof Mike Doyle

10.3 Trial Steering Committee

Dr David Bishop (ST5 in Psychiatry), Prof Mike Doyle (Prof in MH nursing), Dr Arron Peace (Clinical research officer), Dr Clementinah Rooke (Sr Lecturer in MH nursing), PC John Porter (Regional specialist missing persons police officer), Dr Kalyan Seelam (Consultant Psychiatrist and medical lead for older peoples services), Darren Hutchinson (West Yorkshire Police), Claire Fletcher (Advanced Nurse Practitioner, Wakefield Memory Service) and Mrs Julie Warren-Sykes (SWYPT safeguarding lead and associate director of nursing). There will also be a GP from the Wakefield area added to the study in due course and we are currently in the process of recruiting a research assistant for this study.

10.4 Data Monitoring & research governance

Data monitoring will only be undertaken by GCP-trained researchers. All data governance will be undertaken in-line with SWYPT R&D policies and overseen by the study steering group encompassing senior clinicians, clinical researchers, academics, police and experts in safeguarding vulnerable adults.

10.5 Ethics & Regulatory Approvals

Ethical approval will be sought from the Health Research Authority. The study and all participant-facing materials were developed in combination with Alzheimer's Society patient and public involvement.

We are seeking ethics approvals from the Integrated Research Application System (IRAS) and University of Huddersfield School Research Ethics and Integrity Committee. Once approved we intend to start this study immediately.

10.6 Quality Assurance

Participant identification and first approach will be undertaken by NHS clinicians working in the memory services at South West Yorkshire Hospitals NHS Foundation Trust. This will be overseen by Dr David Bishop (ST5 Psychiatry) with supervision from Dr Kalyan Seelam, consultant Psychiatrist and medical lead for memory services within the trust. These are highly experienced in assessment of patients with clinical impairment. All Investigators and staff involved in the study will be trained in GCP, the use of the assessment tools and trial guidance. The Trial Manager will maintain a Trial Master File containing the essential trial documents in accordance with GCP and the EU Clinical Trial Directive. In addition, each site will be provided with an Investigator Site File which will contain the essential trial documents. This will be stored securely in the Research and Development department at SWYPT.

The trial will be carried out in accordance with this protocol and using standardised questionnaires. Trial specific functions will be conducted in accordance with these and will ensure the procedures within the trial are carried out in the same way in each centre.

Monitoring of this trial to ensure compliance with the protocol and Good Clinical Practice will be managed and overseen by the study steering group.

The Chief Investigator and SWYPT R&D Manager will act as custodians for the trial data. All trial data will be stored on a secure NHS password-protected computer and archived in line with the regulations. Trial data may be accessed by those connected to the study team on application to and at the discretion of the CI.

10.7 Data Handling

Data handling will be undertaken by GCP-trained staff at SWYPT. 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 SWYTF.

10.8 Publication Policy

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.

10.9 Financial Aspects

The initial purchase of 25 GPS tracking units has been made by South Yorkshire Police. This project is being supported by clinicians and researchers at SWYPT and academics from the University of Huddersfield at no cost. A successful bid application has been made to the University of Huddersfield seed fund for £5000. This will be used to recruit a part-time research assistant to help with data collection, analysis and publication (NHS afc band 5). A further seed bid has been awarded for £10000 from the NHS Research Capability Funding (RCF) grant to support the study in Wakefield. This will be used to undertake a quantitative analysis involving both focus groups for professionals, in-depth interviews of patients' families, and purchase of up to 25 additional GPS tracking units. The schedule and topic summaries for interviews are attached in the "GPS trackers study interview topics" document.

10.10 Project timetable and milestones

Please see separate GANT chart

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