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Research project Data Nurse: optimizing independence among older adults receiving district nursing care

Submission date
07/10/2025

Recruitment status
No longer recruiting

Registration date
08/12/2025

Overall study status
Completed

Last Edited
08/12/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
As the population continues to age, many older adults prefer to remain independent at home with support from district nurses. However, determining the appropriate care to support independent functioning can be time-consuming, and professionals in district nursing teams often lack a structured method for making data-driven decisions collaboratively with clients. To address this challenge, the Data Nurse intervention has been developed. This intervention includes a Shared Decision Aid designed to help older adults prepare for care choices, an online training program for professionals in district nursing teams focused on person-centered shared decision-making, a dashboard that displays independence data to monitor clients' progress in maintaining independent functioning, and a workshop to train professionals on how to use the dashboard effectively. The aim of the study is to evaluate whether the Data Nurse intervention is practical, user-friendly, and whether it contributes to improved independence for older adults receiving district nursing care.

Who can participate?
Professionals from district nursing teams, clients aged 65 and older who receive district nursing care, and informal caregivers of these clients are eligible to participate in the study.

What does the study involve?
For clients in the intervention group, a professional from the district nursing team will explain the Shared Decision Aid, which takes about five minutes. Clients will then complete the Shared Decision Aid, which takes approximately thirty minutes. If clients have caregivers, the caregivers will complete a short section as well, taking about ten minutes. Clients will also complete questionnaires at the beginning, middle, and end of the study, with a total time commitment of around forty minutes. In summer 2025, clients may be invited to participate in a one-hour home interview to share their experiences.

For professionals in the intervention group, two individuals per team will coordinate the study. They will receive training and ongoing support throughout the study period. These professionals will be responsible for registering clients who wish to participate and will regularly discuss

progress. They will also complete questionnaires at the beginning and end of the study to reflect on their experiences.

Clients in the control group will complete questionnaires about themselves and their experiences with decision-making in their care, with a total time commitment of approximately forty-five minutes.

Professionals in the control group will include one individual per team who will help organize the study. These professionals will register participating clients and ensure that completed questionnaires are stored securely.

What are the possible benefits and risks of participating?
Clients aged 65 and older in both groups will not receive direct benefits from participating in the study. However, their involvement will contribute to improving nursing care for older adults. Professionals in the intervention group will gain knowledge about shared decision-making and the use of data in care, which may help enhance personalized nursing care. Professionals in the control group may also contribute to improvements in personalized care through their participation. All participants, including clients and professionals, will spend additional time completing questionnaires, participating in interviews or focus groups, and using the intervention tools. This may require more time than usual care activities.

Where is the study run from?
The study will be conducted within district nursing teams in four major care organizations across the Netherlands.

When is the study starting and how long is it expected to run for?
June 2025 to November 2025

Who is funding the study?
The study will be funded by ZonMw (Grant Number 10040022010003) (Netherlands)

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
METC 2024.0956 (Not WMO); ZonMw dossier number 80-86300-98-057

Study information

Scientific Title
Feasibility of the Data Nurse intervention in district nursing teams and older adults: evaluation of acceptability, fidelity, implementation factors, and preliminary patient outcomes

Acronym
DNFE

Study objectives
1. To assess the feasibility and acceptability of delivering the Data Nurse intervention among members of district nursing care teams and older adults with district nursing care
2. To evaluate the fidelity of intervention delivery and identify implementation facilitators and barriers
3. To explore preliminary effects of the intervention on patient experiences with SDM, independent functioning, and nurse-led care planning

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 03/06/2025, Medical Ethics Review Committee (METC), Amsterdam UMC (Meibergdreef 9, Amsterdam, 1105 AZ, Netherlands; +31 (0)20 566 9111; metc@amsterdamumc.nl), ref: METC 2024.0956

Study design
Pragmatic non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Data-driven shared decision-making on district nursing interventions to support independent functioning in older adults.

Interventions
Recruitment
The researchers will contact key persons from participating organizations to help distribute recruitment information within the teams. Participation is entirely voluntary. In intervention teams, two volunteers per team will be asked to take on coordinating roles: a lead and a data ambassador. They will support introducing the e-learning on Shared Decision-Making, the use of the dashboard, and managing questionnaires and client registrations. Professionals will recruit existing and new clients (65+) and provide them with information and consent forms. Focus groups with professionals and interviews with clients will take place halfway through the study. In control teams, there will be one lead responsible for client registration and questionnaire management, and clients will also be recruited.

The Intervention
The total duration of the intervention and follow-up is five months. The Data Nurse intervention consists of two parts:
Shared Decision-Making Aid: A booklet where clients and informal caregivers describe their needs, capacities, and goals related to independence, preparing for conversations with healthcare professionals. New clients receive this before intake, existing clients before care evaluations.
Independence Dashboard: A digital dashboard integrated into the client record via the Omaha Classification System, displaying data about client independence and accessible to district nursing teams.

Leads and data ambassadors receive e-learning and workshops beforehand to train and support the team in using both parts. Monthly contact moments with researchers provide guidance and discuss progress.

Data Collection and Protection
Data Collection for Healthcare Professionals:
Healthcare professionals register for the study via Castor, directly connecting them with the Amsterdam UMC researchers. Data collection and analysis are conducted by Amsterdam UMC researchers. Professionals cannot access each other’s questionnaires.

Data Protection for Shared Decision-Making Aid:
Ethical guidelines from the Declaration of Helsinki (2013) are followed. Completed Shared Decision-Making Aids are scanned and stored in clients' electronic records for access by nurses and clients. Additionally, physical copies are collected anonymously in locked boxes at team offices to prevent direct access to electronic records by researchers. Each form is coded to prevent client identification. After data collection ends (after 5 months), forms are digitized and securely stored on a protected drive accessible only to researchers at Amsterdam UMC.

Data Protection for the Dashboard:
A Data Agreement Plan (Non-WMO Clinical Trial Agreement) was developed and signed by all participating care organizations in collaboration with Amsterdam UMC legal advisors.

Data Protection for Focus Groups and Interviews:
Audio recordings are made using a mobile app after informed consent is obtained via signed consent forms. Consent forms are securely stored, and original forms are destroyed after digitization. Personal data are anonymized and confidentially processed. Transcriptions are done using Amberscript and analyzed in MAXQDA. Summaries of transcripts are shared with nurses (member checks) and mailed to older adult participants. Audio files and transcripts are securely stored on protected drives accessible only to researchers at Amsterdam UMC.

Intervention Type
Other

Primary outcome(s)
Intervention Group

1. Feasibility
1.1 Feasibility of the intervention measured using the FIM questionnaire at baseline (T0) and end of study (T1)
1.2 Recruitment rate measured using the progress monitoring log at Month 1
1.3 Retention rate measured using the progress monitoring log at end of study (T1)
1.4 Participation rate measured using the progress monitoring log at end of study (T1)
2. Acceptability
2.1 Acceptability of the Shared Decision-Making Tool measured using the TFA questionnaire (Likert scales) at T1 (end of study) for healthcare professionals
2.2 Acceptability of the dashboard measured using the TFA questionnaire (Likert scales) at T1 for healthcare professionals
2.3 Acceptability of the Shared Decision-Making Tool measured using the TFA questionnaire (Likert scales) at T1 for clients
2.4 Client usage rate of the Shared Decision-Making Tool measured using the progress monitoring log at T1
3. Fidelity
3.1 Fidelity of intervention delivery measured using the progress monitoring log and fidelity checklist (F1) at monthly intervals from Month 1 to Month 5
4. Barriers and Facilitators
4.1 Barriers and facilitators to implementation measured using the Huijg questionnaire at T0 and T1 (for healthcare professionals)
4.2 Technical issues and user-reported problems measured using logbooks in the progress monitor from T0 to T1
5. Shared Decision-Making Experience
5.1 Client experience of shared decision-making measured using the CollaboRATE questionnaire

at T0 and T1
5.2 Client experience of shared decision-making measured using a custom questionnaire and interviews at T1 and during summer 2025 (midpoint)
5.3 Healthcare professionals' experience of shared decision-making measured using a custom questionnaire and focus groups at T1

Control Group

1. Shared Decision-Making Experience (Clients)
1.1 Client experience of shared decision-making measured using the CollaboRATE questionnaire at T0 and T1
1.2 Client experience of shared decision-making measured using a custom questionnaire at T0 and T1
2. Use of Data by Healthcare Professionals
2.1 Use of self-reliance and care data in decision-making measured using a custom questionnaire at T0
3. Care-as-usual (Professionals)
3.1 Current decision-making practices measured using telephone interviews with approximately 20 professionals at T0
3.2 Use of Omaha System data in evaluating independence and decision-making measured using custom questionnaire at T0

Key secondary outcome(s))

Here is the revised version with sub-list numbering and no formatting:

Intervention Group

1. Secondary Outcomes from Electronic Health Records
1.1 Number of weekly nursing care contacts measured using data extraction from electronic client record at T0 and T1
1.2 Total hours of district nursing care delivered per week measured using data extraction at T0 and T1
1.3 Type of nursing care provided (face-to-face, video call, telephone, care technology) measured using data extraction at T0 and T1
2. PROMs
2.1 Client-reported outcomes on perceived health measured using PROMs from the Shared Decision-Making Tool and TOPICS-SF at T0 and T1
3. Target Scores
3.1 Percentage of care actions focused on promoting independence measured using client records at T1
3.2 Percentage of improved scores per domain (from intake to evaluation) measured using client records at T1 and second evaluation
3.3 Percentage of clients who achieved their target scores measured using client records at T1 and second evaluation

Additional Activities – Intervention Group

Client burden
1.1 Shared Decision-Making Tool usage time: approximately 30 minutes (plus 10 for caregivers)
1.2 Questionnaire administration (T0): Baseline, acceptability, CollaboRATE, shared decision-making form (approximately 35 minutes)
1.3 Questionnaire administration (T1): CollaboRATE, shared decision-making form

(approximately 20 minutes)
1.4 Interview: 60-minute home interview during Summer 2025 (optional)
2. Healthcare professionals' burden
2.1 Questionnaires (T0 and T1): acceptability, feasibility, barriers/facilitators, experience with Shared Decision-Making Tool (total approximately 35–40 minutes each time)
2.2 Monthly progress meetings: 30–60 minutes with researchers (Months 1–5)
2.3 Dashboard discussions in client meetings: approximately 15 minutes monthly
2.4 Focus groups
2.4.1 Four focus groups (dashboard barriers) – 8 to 12 participants, 90 minutes
2.4.2 Two focus groups (shared decision-making) – 7 to 10 participants, 90 minutes

Control Group

1. Secondary Outcomes from Electronic Health Records
1.1 Number of weekly nursing care contacts measured using data extraction from electronic client record at T0 and T1
1.2 Total hours of district nursing care delivered per week measured using data extraction at T0 and T1
1.3 Type of nursing care provided (face-to-face, video call, telephone, care technology) measured using data extraction at T0 and T1
2. Target Scores
2.1 Percentage of care actions focused on promoting independence measured using client records at T1
2.2 Percentage of improved scores per domain measured using client records at T1 and second evaluation
2.3 Percentage of clients who achieved their target scores measured using client records at T1 and second evaluation

Completion date
15/11/2025

Eligibility

Key inclusion criteria
1. District Nursing Care Organizations:
1.1 Participation in the Data Nurse consortium (ZonMw project number: 80-86300-98-057)
1.2 Ability to implement the Independent Functioning Dashboard into their electronic client record system
1.3 Sufficient willingness and capacity to participate in the study

2. District Nursing Teams:
2.1 Teams must be affiliated with the Data Nurse project
2.2 For the intervention group, teams must have access to the Independent Functioning Dashboard

3. Clients:
3.1 Individuals aged 65 years or older
3.2 Currently receiving district nursing care from a team participating in the Data Nurse project

4. Informal Caregivers:
4.1 Informal caregivers of clients who are receiving district nursing care from a participating team

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
150 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. District Nursing Teams:
1.1 Nursing teams currently participating in other healthcare-related research studies
2. Clients:
2.1 Clients with a condition that causes irreversible decline in independence, such as:
2.1.1 Advanced dementia (stage two or higher, according to Alzheimer Nederland)
2.1.2 Advanced Parkinson’s disease
2.1.3 Multiple sclerosis
2.2 Clients with a life expectancy of less than 3 months
2.3 Clients and/or informal caregivers who have insufficient proficiency in Dutch to provide informed consent
2.4 Clients currently participating in other healthcare-related research studies

Date of first enrolment
03/06/2025

Date of final enrolment
15/06/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC Department of Geriatrics Location AMC
Meibergdreef 9
The Netherlands
Amsterdam
Netherlands
1105 AZ

Study participating centre
Utrecht University of Applied Sciences (Hogeschool Utrecht)
Padualaan 97
Utrecht
Netherlands
3584 CH

Study participating centre
Vilans, Center of Expertise for Long-term Care
Churchilllaan 11
Utrecht
Netherlands
3527 GV

Sponsor information

Organisation
Amsterdam University Medical Centers

ROR
https://ror.org/05grdyy37

Funder(s)

Funder type
Not defined

Funder Name
ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: protected disk Amsterdam UMC L disk at Amsterdam UMC (L:\Basic\diva\Ouderengnk\Datanurse).
• Type of data: Coded participant-level data, digital and paper questionnaires, interview transcripts (coded), statistical analysis outputs (R), audio recordings
• Availability: Data will be available upon reasonable request after publication and preserved for at least 10 years
• Access criteria: Data access is restricted to researchers with a valid research purpose. Access will be granted following a review by the principal investigator (PI) and signing of a Data Sharing Agreement (DSA)
• Shared with: Academic researchers or affiliated research institutions
• For what types of analyses: Secondary analyses in line with the original informed consent (e.g., studies on older adults, decision-making in care, Omaha classification, etc.)
• Mechanism: Secure data transfer via SURF Filesender; access under DSA only
• Consent: Informed consent includes provisions for data reuse
• Data anonymisation: Data are coded (pseudonymised), not fully anonymised. Identification is only possible via a subject ID log maintained separately and securely by healthcare professionals
• Legal/Ethical restrictions: Data cannot be made public due to privacy risks. Sharing is conditional on ethical compliance and legal review
• Other comments: Metadata, protocol, statistical analysis plan, and data management documentation are archived and may be shared upon request to ensure transparency

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/10/2025	No	Yes
Participant information sheet			10/10/2025	No	Yes
Participant information sheet			10/10/2025	No	Yes
Participant information sheet			10/10/2025	No	Yes