



Prevention of Dehydration in Independently Living Elderly People at Risk: A Study Protocol of a Randomized Controlled Trial

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ABSTRACT

Background: Dehydration of elderly people living independently is a very important public health issue. This study compares two interventions to prevent dehydration in elderly people at risk: an educational intervention and an educational intervention in combination with a drink reminder device.

Methods: This is an experimental two-armed parallel study. A Public Health Service develops the interventions and will be partnering with a general practice and a university to evaluate the effects. Two groups – all people aged 80 years and older, and people of 65 years and older who have cardiovascular disease – receive a letter from the general practice in which they are asked whether they want to participate in the study and if so to return the form. People who want to participate and whose daily fluid intake is insufficient are randomized to receive either the educational intervention or the educational intervention in combination with a drink reminder device. The participants are asked to fill in a questionnaire before the intervention, 6 weeks after the start of the intervention and 6 months after the start (or after the end) of the intervention. Changes between the two groups in fluid intake, knowledge, awareness of the risks of dehydration, and quality-of-life will be tested by Linear Mixed Model analyses.

Conclusions: This study will improve the knowledge of the effectiveness of interventions designed to prevent dehydration in elderly people.

Keywords: Dehydration, drink reminder device, elderly, fluid intake, study protocol

INTRODUCTION

Dehydration of elderly people can cause cognitive and mental dysfunction (e.g., delirium). It increases the risk

of thrombo-embolic complications, bladder infection, respiratory infection, kidney stones, fever, obstipation, low blood pressure, and medicinal intoxication.^[1-6]

Depending on the definition of dehydration, between 6% and 30% of people aged 65 years and older who are hospitalized are dehydrated.^[2] In 1.5% of these cases, dehydration is the primary cause for the hospital admission. The fatality rate from dehydration can rise as high as 50%. A major cause of dehydration among elderly people is insufficient fluid intake.^[1,7,8] In literature^[1-6] it is mentioned that the most important strategy for preventing dehydration of elderly is to

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achieve sufficient fluid intake. In earlier research,^[6] elderly themselves stated that forgetting to drink is an important reason why they drink insufficient. In this research, 134 elderly (independently living) were asked to fill in a questionnaire. Two of the reminder methods, they preferred, were receiving information from their family doctor and a reminder device.^[6] Since these interventions are currently not available^[7-10] we will develop them ourselves. We did not find other studies on the effect of increased awareness on fluid intake and/or health outcomes.

The aim of this study was to compare two interventions to increase fluid intake in elderly living independently who are at risk of dehydration: Education on its own and education in combination with a drink reminder device, called Obli.^[11] This article describes the design of the study.

METHODS

Study design

This study is a randomized controlled trial. It is an experimental two-armed parallel research project.

A Public Health Service develops the interventions and will be partnering with a general practice and a university to evaluate the effects. Education material is already developed. In the project, this material will be integrated into the general practice, and work instructions on how to carry out the interventions will be developed.

Interventions

Intervention 1: Education

The elderly people in this group will receive information from a practice nurse during a home visit or consultation. The practice nurses will visit the elderly person just once for about half an hour. They will use the instruction tools (with points to include in the education) and education material.

The health education will contain information on the recommended fluid intake (and how many cups/glasses this are), the risk of dehydration, and the possible solutions. If daily fluid intake of the elderly is insufficient, they will receive information materials on the subject and are shown how to incorporate sufficient fluid intake into their daily routines. This information is piloted on three elderly of different ages and backgrounds. We checked if the information was clear.

Intervention 2: Education in combination with a drink reminder device

The elderly in this group will receive the same information as the elderly in intervention 1, as well as a drink reminder device, which they are asked to use for a

period of 6 weeks. A caregiver or family member can be present at the demonstration of the device. The drink reminder device (called Obli) measures fluid intake and emits a visual and auditory signal (red light and beep) if the daily fluid intake is insufficient, so the elderly can adjust their drinking behavior accordingly. The intensity of the signal can be adjusted to the preference of the person in question. The device registers the quantity of fluid taken from the decanter placed on the device base. If the person drinks coffee/tea (not from the decanter or not at home), a button on the device can be pushed so this fluid intake is also measured.

When people use fluids outside their homes, they can push the button on the Obli when they return at home, so these intakes are counted too. The Obli cannot be stored in the refrigerator, but cooled drinks can be used and added by pushing the button on the device, so safety issues do not apply.

The device registers fluid intake and sends the data to a remote computer from which the practice nurse can monitor fluid intake. When the monitoring of the device shows that the elderly do not drink sufficiently the practice nurse will contact the elderly by telephone and if needed will give some advice. If the device fails or people have difficulty with it, there is a helpline; Fresh Idea Factory (the provider of the device) will provide this. The elderly can also contact the project leader if they have any questions. Employees of the Fresh Idea Factory will also check themselves if the device works and in case of any problems, they will contact the elderly.

With the consent of the elderly, caregivers or care workers who visit frequently will also be informed about the project.

Inclusion and exclusion criteria

Persons who are 80 years and older or patients with cardiovascular disease, aged 65 years and older, are included in the study. These inclusion criteria are chosen on the basis of known risk factors of dehydration^[1] in literature and the possibility to select these factors from the general practitioner's patient files.

We only include elderly with the consent of their specialist and general practitioner.

Known risk factors for dehydration are: Age (≥ 80), Alzheimer disease, Parkinson disease, infections, cardiovascular disease.^[1] With patients with the cardiovascular disease, we mean patients who had a heart attack or have a cardiovascular disease and are monitored by the general practitioner. We include patients with cardiovascular disease because they are at risk whatever their age above 65 years. We only can search in the digital files of the general practices for age

and cardiovascular disease. The other known risk factors are not present in the files.

Patients who are not able to correspond in Dutch, who have cognitive impairments that would make them unable to answer the questionnaire, or who had kidney or bladder disease are excluded from the study. We will also exclude elderly on strict fluid restrictions and Alzheimer patients because they cannot participate in the interventions because of cognitive impairments. Finally, we exclude people living in nursing homes because people living in nursing homes are not the groups the Regional Public Health Service West Brabant is focused on.

Recruitment of participants

The following partners are participating in the project: Four general practitioners and three practice nurses, a public health service, a university, and the innovation company that designed the Obli.

The four general practitioners will select from their patient files the elderly people who are at risk of dehydration. The search terms are birthdate (for 65 years and older) and cardiovascular disease.

These selected patients will receive a letter from the general practice with information about dehydration and details about the project. If the elderly person thinks she/he does not drink enough and wants to participate, she/he is asked to indicate the amount of fluid she/he normally drinks every day on the form and return this form to the researcher. If too few people have responded after the first letter, a reminder is sent.

We will compare the daily fluid intake of the elderly who have responded with the amount that is recommended for elderly at risk, ≥ 1.7 L or nine cups/glasses a day.^[1]

The elderly whose fluid intake is insufficient are contacted by the researcher to give more information if needed and to confirm if they definitely want to participate in the study. The elderly who definitely want to participate are visited by the practice nurse and are asked to sign an informed consent form. The elderly who want to participate but already drink sufficient quantities will receive a letter explaining that they will not be included in the study because their fluid intake offers no cause for concern.

People whose fluid intake is insufficient, but who withdraw from the study because they ultimately are no longer willing or able to participate will receive information by phone about their risk of dehydration, but will not participate in the interventions. To retain respondents participating in the study, each respondent in both groups will receive the drink reminder device free of charge after the end of the study.

Randomization

The elderly people are randomly assigned to either intervention group 1 or 2. The allocation will be done by

the second author, a senior researcher. The elderly have been assigned a number, so their names are not known. Randomization will take place by means of selection through a computer software device. The allocation will take place when the elderly have agreed to take part in the study. It is a parallel study. We will analyze the baseline characteristics before starting the interventions, so they do not influence the allocation arm. We will use an allocation ratio of 1:1.

Complete blinding is not possible because questions need to be asked about the experiences of the elderly with the interventions. Their answers will indicate which intervention they received.

Outcomes

All participating elderly people are asked to fill out a questionnaire. We measure fluid intake, the knowledge, and awareness of the risks of dehydration, and the quality-of-life at the following moments:

- At baseline, during a home visit or consultation with the practice nurse, before the intervention starts
- Six weeks after the start of the interventions during a home visit by the health promoter of the public health service
- At 6 months' follow-up during a home visit by the health promoter.

Since, to the best of our knowledge, no validated questionnaires are available to measure fluid intake and knowledge and awareness of the risks of dehydration, we designed one for measuring these parameters in our study. We use the same questionnaire for all the three measurements.

These questions have been piloted by three elderly people of different ages and backgrounds.

We checked if the questions were clear and answering the questions did not take too long.

Primary study parameters / outcome of the study

The main parameter on individual and group level is daily fluid intake (the quantity of cups/glasses of fluid consumed daily). Fluid intake is measured by a recall measure; open-end questions regarding the intake quantity of different kinds of fluid (including water, coffee, tea, milk and soda, but excluding alcoholic drinks) on the day before completing the questionnaire. The answers on the questionnaire regarding the quantity of different fluids they drink are added up to achieve a single overall score of cups/glasses a day and a total quantity of cubic centimeters (cc) a day.

We will analyze effects at 6 weeks and 6 months. The primary outcome will be the difference between the intervention and control groups.

Secondary study parameters / outcome of the study

The other parameters are knowledge and awareness of the risks of dehydration, quality-of-life, and experiences with the interventions.

Knowledge about the risks of dehydration is measured by four items [Table 1], with which the elderly can agree or disagree on a three-point scale (“this is correct,” “this is not correct” or “I don’t know”).

Awareness of the risks of dehydration is measured by three questions [Table 1].

The score of correct answers on the knowledge and awareness questions in the questionnaire are converted into an overall score representing knowledge and awareness.

We will gather information at baseline about the knowledge of the risk of dehydration and quality-of-life. A change in knowledge will be reflected in a change in the knowledge score.

In an earlier research,^[6] we used the same knowledge questions for the elderly. The level of correct answers was low, so we expect that the level of knowledge at baseline will be low for our research groups too. We expect that the questionnaire will be sensitive enough to measure the difference in knowledge after the interventions.

Increasing knowledge and awareness is a first step in changing behavior^[12] In literature,^[1] it is mentioned that

the most important strategy for preventing dehydration of elderly is to achieve sufficient fluid intake. To do this, people need to be aware of the risks of insufficient fluid intake.

To measure the quality-of-life, the EuroQol questionnaire^[13] is used. This validated questionnaire provides an index value for health status (a measure for quality-of-life) and is also suitable for elderly people. It contains five questions with answers on a three-point scale. These questions include mobility, self-sufficiency, daily activities, pain, and mood. The questionnaire also contains a general question about the participants’ self-rated health state on a vertical, visual analog scale where the endpoints are labeled “Best imaginable health state” and “Worst imaginable health state.” The participants are asked to give a score from 0 to 100.

To measure the experiences of the elderly with the interventions, we will conduct a semi-structured interview at the first measurement 6 weeks after the start of the interventions. Process evaluation of the project will be conducted by interviewing the practice nurses, general practitioners, and the RPHS workers.

Statistical analyses

Sample size and power

A power analysis was performed to determine the sample size to detect a difference between the two intervention groups with respect to daily fluid intake. The method we used was Linear Mixed Models.^[14] It was assumed that the interventions will lead to a difference of at least two cups between the two groups. This difference was chosen after deliberation with the general practitioner, practice nurses, and the scientific staff. Since the Obli will give the elderly a constant reminder to drink sufficiently, we are convinced this expected effect is realistic.

With a power of 90% at a 0.05 alpha level, we concluded that the intervention groups should at least consist of 21 persons in each group. Taking into account 15% attrition over the trial period, 25 persons need to be recruited for each group, 50 in total.

We estimated that we have to approach about 500 elderly people, assuming that 20% of the elderly do not drink enough fluids and 60% of the elderly want to participate in the interventions.^[6]

The general practitioners in our study have 11.600 patients in their care, so it is feasible to recruit this number of people within the parameters of the study. There are sufficient elderly, males and females and elderly with cardiovascular disease in their patient population to include in the study.

Table 1: Questions on knowledge and awareness

| | Possible answers |
|--|---|
| Questions on knowledge | |
| “When your fluid intake is too low, you always get thirsty” | This is correct This is not correct I don’t know |
| “When it is hot, your fluid intake should be higher than on normal days in order to prevent dehydration” | This is correct This is not correct I don’t know |
| “When you drink alcohol you lose more fluid than you consume” | This is correct This is not correct I don’t know |
| “When you are dehydrated, you will urinate more than normal” | This is correct This is not correct I don’t know |
| Questions on awareness | |
| “Do you think you drink sufficient quantities?” | Yes (correct/incorrect) No (answer depends on) I don’t know (actual fluid intake) |
| “Do you think you are at risk of getting dehydrated?” | Yes (correct/incorrect) No (answer depends on) I don’t know (actual fluid intake) |
| “And if so, what is the reason you think you are at risk?” | Because of my age Because of my illness Another reason, namely... |

The correct answer in bold

Analyses

Descriptive analyses

- Description of the study population on demographic parameters (age, gender, living accommodations, type of disease)
- Quantity of fluid intake, knowledge, and awareness of the risks of dehydration, and quality-of-life before and after the interventions.

Longitudinal analyses

We will use Linear Mixed Models^[14] to compare the changes in mean total scores on fluid intake and knowledge between the two intervention groups at 6 weeks and 6 months after the interventions.

DISCUSSION

Potential strength of the study etc

The present study has several potential strengths. These include the potential benefits of the intervention effects, the randomization approach and the use of the checklists and questionnaires.

Effects of the interventions

The direct benefit of the interventions is aimed at increasing fluid intake, thus reducing the risk of dehydration. The indirect benefit is the enhancement of knowledge and awareness of the elderly people on the subject.

Randomization approach

An important strength of this study is the randomization approach, in which allocation is handled by an automated computerized process.

Use of checklists and questionnaires

All participating nurses are given the same instructions on how to provide the educational intervention. They also receive a checklist of topics that should be covered in the intervention. This promotes the uniform use of the interventions and reduces the risk of interpersonal variation and effects on the outcomes. The health promoters also receive instructions on how to interview the elderly in order to measure the effects of the intervention correctly. They will conduct the first home visits together, so they can learn from each other and synchronize their approach. The questionnaires contain relatively few open questions in order to lower the risk of differences in interpreting the answers. Finally, we use a validated questionnaire to measure the quality-of-life.

Potential limitations of the study

The present study has some potential limitations. This includes no use of a control group without any intervention, the risk of excessive fluid intake, the influence of alcohol and coffee intake and excluding patients with kidney/bladder disease and nursing home residents.

No control group without any intervention

Since it would be ethically indefensible to screen for insufficient fluid intake and not take action if a problem is identified, a control group of elderly people who do not drink enough fluids and do not receive any intervention has not been included in this study. The Medical Ethical Committee agreed with us on this. However, the lack of a real control group means that we will not be able to exclude influences from outside the intervention that might affect the results. We have tried to minimize this risk by including a group of elderly people who only receive education (who could, therefore, be seen as a control group) and by performing the interventions in the same time period.

RESULTS

It's a study protocol, so results are not yet applicable.

The lack of a control group also means that the effect of the group with the device has to be much higher than the effect of the group with only education to achieve significant differences.

The Obli will constantly remind the elderly to drink sufficiently; so we believe it to be much more effective than education alone, given only at one single moment.

The risk of excessive fluid intake

Encouraging increased fluid intake may cause the elderly to increase their intake to a level above what is considered healthy. We will, therefore, ask all participants if a specialist has advised a minimum or maximum fluid intake and take this into account when instructing the person. In the group with the reminder device, we also use an alarm. The signal on the drink reminder device can be adjusted to a minimum or maximum daily fluid intake to prevent excessively low or high fluid intake.

The use of a recall measure

We will assess fluid intake using a questionnaire (recall measure). We ask the elderly which kind of fluids and how many they used the day before answering the questionnaire. Other methods, like asking them to fill in a diary or observe their behavior all day is too demanding for the elderly and takes too much time. The Medic Ethical Ethics Committee agreed with us on this.

The influence of alcohol and coffee intake

In the study, we ask the participants how much alcohol they drink. However, we do not include alcohol intake in total fluid intake. Alcohol decreases the body's antidiuretic hormone production, which the body uses to reabsorb water. With lower levels of antidiuretic hormone available, the body loses more fluid than normal through increased urination.^[15] As the consequences of alcohol intake for the minimum recommended daily intake are uncertain, we do not include alcohol in total fluid intake. If the person

drinks alcohol, it is in any case evident that more than the minimum recommended daily fluid intake will be required.

Although coffee is often thought to have a negative effect on fluid balance, research^[15] shows that coffee has no significant effects unless consumed in very large quantities. We, therefore, do include coffee in total fluid intake.

No patients with kidney/bladder disease or nursing home residents
Our study does not include patients with kidney or bladder disease or elderly patients living in nursing homes. These groups are also at risk of dehydration. Patients with kidney/bladder disease, however, already receive specific advice and attention regarding their fluid intake from their treating physician. Elderly patients living in nursing homes do not belong to the target population of the RPHS of West-Brabant and the general practitioners.

ETHICS AND DISSEMINATION

This study has been approved by the Dutch Medical Ethical Ethics Committee METOPP (METC M521, NL45169.028.13).

The capacity of the elderly is assessed by the practice nurse who visits the elderly and by consulting the patient files. It is also possible for family members of elderly to indicate if their relative cannot consent. If the person does not have the capacity, we will not include him/her, even when he/she wants to. People need to understand how the interventions work to be able to participate.

After the elderly give consent, they can at any time change their minds and withdraw from the study. This is explained to them.

CONCLUSIONS

Prevention of dehydration is of great public health importance. This project can improve fluid intake in elderly people at risk. It can also result in more efficient care and promote the use of technological support and E-health. Early detection makes it possible to prevent dehydration-related hospitalization of elderly people. It also enhances their self-sufficiency, allowing the elderly to live independently at home for longer.^[16]

The results regarding the effectiveness of the interventions will contribute to the knowledge of effective factors in preventing dehydration in elderly people living at home.

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