THE EFFECTS OF A MOBILE SAFETY ALARM ON GOING OUTSIDE, FEELINGS OF BEING UNSAFE, FEAR OF FALLING AND QUALITY OF LIFE IN COMMUNITY-LIVING OLDER PERSONS: A RANDOMISED CONTROLLED TRIAL

Alice C. Scheffer
Wilma J. Scholte op Reimer
Nynke van Dijk
Barbara C. van Munster
Ameen Abu-Hanna
Marcel M. Levi
Sophia E. de Rooij

Submitted
CHAPTER 7

FEAR OF FALLING IN OLDER PATIENTS
ABSTRACT

Objectives: To investigate the effects of a mobile safety alarm on the frequency of going outside and experiences about the fear of falling (FOF), feelings of being unsafe, and quality of life (QoL) in older persons.

Design: Two-armed, open, randomised, controlled trial.

Setting: Community-dwelling older persons in the Netherlands.

Participants: A total of 203 older persons ages 65 years old and older, using a home-based alarm, who were randomly assigned to receive a mobile alarm or care as usual.

Intervention: Randomly assigned mobile safety alarm with built-in drop sensor using a positioning system via a cell phone network. The mobile alarm was provided for six months.

Measurement: The primary outcome was a change in the frequency of going outside. Secondary outcomes included fear of falling (Visual Analogue Scale [VAS]-FOF), feelings of unsafety (VAS for Feeling Unsafe) and QoL. Outcome measurements were recorded by telephone interviews at baseline and at one, two, four and six months after inclusion.

Results: In this study, 203 participants were included: 100 participants (mean age 80.8 ± 9.0 years old) received an extra mobile alarm, and 103 control participants (mean age 81.2 ± 9.3 years old) received care as usual (continuation of a home-based alarm). In the intervention group, 58 participants completed the trial, in contrast to the 77 participants in the control group. Analyses according to intention-to-treat principles showed no increase in the frequency of going outside in the intervention group.
**Conclusions:** This study was the first study using an outdoor mobile safety alarm that was conducted with a large number of vulnerable older persons. The mobile alarm system, the Butler, was not shown to have an added value, compared to the usual home-based alarm. The greater number of participants in the intervention group withdrawing from the intervention might explain why there were only slight differences between the two study groups. Also, participants from the intervention group perceived some user-unfriendliness with the Butler.
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INTRODUCTION

Due to socio-demographic changes, the number of older persons in Western countries is increasing. The Dutch population consists of 16.7 million people, of whom 15.3% are older than 65 years old.\(^1\) Estimations are that, by the year 2020, this proportion will grow to 19.7%, corresponding to 3.3 million people.\(^2\) Also, individual life expectancy is steadily increasing due to improvements in medical science and health care. Increased life expectancy, however, does not necessarily translate into healthier lives, as with age, the prevalence of chronic disease increases, affecting older peoples’ independence and well-being.\(^3\) One of the biggest challenges for a society with an aging population is to create conditions with which older persons may stay healthy and remain at home as long as possible. To achieve this goal, it is important that older persons are active and mobile. The lesser ability of older persons to move around effectively in their homes and communities is an early predictor of physical disability.\(^4\)

To help older persons move around more freely and to promote their well-being, different kinds of support are needed, and a wide range of technologies and services have already been developed and implemented. Nevertheless, these new technologies do not always adapt to the needs of potential users in terms of functionality and usability.\(^5\) Existing research has concentrated on the design and development of intelligent, supportive technology, such as safety alarms or response systems using image-based sensors and video cameras that detect falls in the home.\(^6\) Education, income and cognitive abilities are important prerequisites for the use of new technologies by older persons.\(^5\)

Safety alarms are often provided to older persons to make it possible for them to stay at home as long as possible. By pressing an alarm button that is fixed on a device that resembles a necklace, the alarm is activated. Employees of an emergency call centre answer via a phone with a loudspeaker in the client’s home. Homecare staff is directed to the client and acts on these alarm calls. Current safety alarms are limited in terms of range and cannot be used outdoors.\(^7\) Consequently, the mobility of older persons may be limited, and they may feel more housebound.
By replacing a home-based alarm with a mobile system, users are able to move freely anywhere, including outdoors.

Research that has been undertaken on mobile safety alarms has used satellite-based GPS technology. GPS receivers can provide information about location, speed of movement and elevation encountered. However, GPS reception is frequently interrupted in ‘urban canyons’, under heavy tree canopies, and inside large buildings or underground garages. For these reasons, a mobile safety alarm, called the Butler, was developed, using a new kind of positioning system. The activity and safety of the Butler have been investigated at an earlier stage (unpublished data). The aim of this study was to identify the clinical relevance and practicality of this mobile safety alarm. In particular, we aimed to study a possible positive effect of the mobile alarm on the frequency of going outside of older persons and on their experiences concerning safety, fear of falling (FOF) and quality of life (QoL).

**METHODS**

**TRIAL DESIGN**

This study was designed as a two-armed, randomised, controlled trial and was conducted between July 2009 and March 2010. Follow-up data were collected at one, two, four and six months after the start of the intervention. The study was presented to the Medical Ethics Committee of the Academic Medical Centre, which waived the need for ethical approval because no medical interventions occurred. All included persons consented to participate.

**PARTICIPANTS**

Participants were recruited by a direct mailing to older persons residing in specific areas of the city of Amsterdam. These persons were all clients of a health care organisation that offers alarm services. Clients already using a home-based alarm, who were interested in trying out a mobile safety alarm, were asked to return a pre-stamped reply card. Interested clients were then contacted by phone for
eligibility screening. The inclusion criteria included being older than 65 years of age, having a home-based alarm and being able to go outside alone.

**RANDOMISATION**

A physician not involved in the recruitment or data collection developed a computer-generated randomisation sequence. After inclusion, all participants who satisfied the inclusion criteria and volunteered to participate were randomly assigned 1:1 after stratification, upon the presence or absence of feelings of unsafety and FOF, to the intervention group or to the control group. Participants assigned to the intervention group received a mobile alarm for a period of six months, in addition to their home-based alarm. Those people assigned to the control group received a continuation of the home-based alarm service. It was not possible to blind participants or researchers to the randomisation results.

**INTERVENTION AND DESCRIPTION OF DEVICE**

The intervention consisted of a mobile safety alarm with a built-in drop sensor, the Butler. The alarm went off by pressing a button. An integrated, hands-free function allowed the user to speak to the personnel of the alarm service, even if the user did not hold the device to his or her ear. If the user fell, the system also automatically registered this event and independently made a call to the alarm service. The Butler used another technology as a positioning system. The user of the alarm was located in three steps: first, the person’s rough location was found via the cell phone network; second, from close range, his or her position was pinpointed via an integrated tracking device; and third, a beeping sound emanated from the device. This procedure allowed first-aid providers to find the person in need reliably, even in situations in which conventional positioning systems such as GPS fail, such as in buildings, ditches or underground garages. For this study, the Butler could only be used during working hours on weekdays and within a certain distance from the alarm service. Participants, when using the Butler, were required to be found by the personnel of the alarm service within 30 minutes after pressing the alarm.
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Data collection

Data on age, sex, social status, living arrangement, general health status, cognitive status, mobility and fall history (fall incidents in the previous three months) were assessed at baseline. At baseline and at one, two, four and six months after enrolment in the study, self-reported data were collected, using questionnaires and structured telephone interviews. Non-adherent participants in the intervention group were also approached at all follow-up points. Data on falls were collected prospectively with use of fall calendars. Participants were asked to return their calendar pages every month. We also collected data on the number of times the home-based alarm was used by the participants during the trial period and in the six months before this trial.

Outcome measurements

The primary outcome parameter was a change in the frequency of going outside. The secondary outcomes were FOF, feelings of unsafety outside and quality of life (QoL). Going outside was assessed using the question ‘How often do you go outside?’ The answer options were: daily, weekly, monthly, or never. To assess FOF, the VAS for Fear of Falling (VAS-FOF) was used. The VAS-FOF uses a numeric scale (1-10) to measure the perceived fear of falling after a fall (Figure 1). The participants were instructed to select the number that best reflected the intensity of FOF experienced, with 1 representing no fear of falling and with 10 representing an extreme fear of falling. For measuring feelings of unsafety when going outside, a numeric scale was also used. The VAS for feeling unsafe (VAS-safety) uses a numeric scale (1-10) to measure the perceived feelings of unsafety when going outside. The participants were instructed to select the number that best reflected the intensity of the feelings of unsafety experienced, with 1 representing not feeling unsafe at all and with 10 representing feeling very unsafe. Health status was assessed by the question ‘How is your health status at this moment?’ The response options were as follows: excellent, very good, good, fair, or bad. In addition to this question, the EQ-VAS-QoL was used. The EQ-VAS-QoL generates a self-rating of health-related quality of life on a 20-centimetre, vertical, graduated visual analogue...
scale. The end points are labelled ‘best imaginable health state’ at the top and ‘worst imaginable health state’ at the bottom, having numerical values of 100 and 0, respectively. The respondent rates his/her health state by drawing a line from the box marked ‘your health state today’ to the appropriate point on the EQ-VAS-QoL (http://www.euroqol.org). The reliability and validity of the EQ-VAS-QoL has been established in various studies.\textsuperscript{9-11} Fall data were collected prospectively for safety monitoring using fall calendars because increased activity, measured by an increase in the frequency of going outside, might have led to an increased fall risk due to greater exposure. Participants were asked to return a calendar page every month. Non-responders were reminded by telephone. Data on the use of the home-based alarm, during the trial period and in the preceding six months, were collected by checking the database of the alarm service. Finally, data on age, sex, social status, living arrangement, general health status, cognitive status, mobility and fall history (fall incidents in the previous 3 months) were assessed at baseline.

**Statistical analyses**

To find a 15% increase in the frequency of going outside, with a power (1-\(\beta\)) of 80% and an alpha of 5%, 92 participants were needed in each group. Taking a dropout rate of 10% into account, 101 participants were required for each group. All analyses were performed according to the intention-to-treat principle, using all available data on each participant according to his/her original group assignment, irrespective of the intervention being used or not. Additionally, a per-protocol analysis was performed on those participants fulfilling the adherence criteria. Sufficient adherence was defined as having received the intervention for the whole study period of six months. Socio-demographic data were expressed as percentages for categorical data, as means and standard deviations (SD) for normally distributed numerical data and as medians and quartiles for non-normally distributed numerical data. The baseline data were compared between the intervention group and the control group using a chi-square test for categorical and independent samples and a t-test for numerical data. Changes in the frequency of going outside, FOF, feelings of safety and QoL over time were compared between
groups using the Friedman test. Data were analysed using SPSS, version 16.0 (SPSS Inc., Chicago, Illinois, USA) and R, version 2.10.1 (R Development Core Team, Vienna, Austria). A p-value of <0.05 was considered to indicate a statistically significant difference.

RESULTS

PARTICIPANTS
Figure 1 shows the number of people assessed for eligibility and the progress of the participants through the trial. A total of 656 older people using a home-based alarm were invited to participate in the trial, and 245 were interested in a mobile safety alarm. Of the 245 eligible, 42 were excluded because they indicated not being interested anymore at the beginning of the study. Of the 203 enrolled participants, 100 were randomly assigned to the intervention group and 103 to the control group. The intervention and control groups were comparable with regard to most baseline characteristics (Table 1). During the trial, 68 participants dropped out of the study: 42 (42%) in the intervention group and 26 (25%) in the control group. The dropout rate was greatest directly after the intervention, and the reasons for withdrawal are presented in Figure 1. No statistically significant baseline differences (p<0.05) between dropouts and participants who completed the trial were present in either study group with respect to age, sex, living situation, cognitive status, perceived general health, fall history, fear of falling and not going outside because of feelings of unsafety. At baseline, participants who completed the intervention went significantly more frequently outside (p=0.03) and felt safer outside than the dropouts (p=0.04). In the intervention group, the foremost reason for dropout was that participants found the Butler too big and too heavy to carry. The data for all follow-up points were complete for 56 participants in the intervention group and for 56 participants in the control group; the follow-up data were missing from seven and 13 participants in the intervention and control groups, respectively.

Figure 2 shows the effects on the primary outcome, with participants shown in the intention-to-treat group analyses. Compared to the baseline values, there was
a trend toward a higher frequency of going outside in the control group. As shown in Table 2, the differences between baseline and all follow-up points for going outside more often were not significant between the two groups. The analysis of secondary outcomes did not yield significant differences in changes in FOF or feelings of unsafety (Table 3) or the experienced QoL (results not shown). At baseline, 19.6% of the participants in the intervention group considered their health status to be very good or good. In the control group, this percentage was the same. At six-month follow-up, these percentages were 28.6% and 27.5%, for the intervention and control groups, respectively (p=0.28). During the study period, fall calendars were returned by 36% of the participants in the intervention group and by 31.3% of the participants in the control group. In both the intervention group and the control group, 3.8% of the participants reported 1 or more fall incidents during the trial period. In the six months prior to our study, 89.4% of the participants, both from the intervention group and control group, never used the home-based alarm. During the trial period, 13.8% of the participants from the intervention group used the home-based alarm more often than in the preceding six months. In the control group, this percentage was 3.9% (p=0.05). Per protocol analyses did not change the studied effects of the mobile alarm (data not shown).

**DISCUSSION**

The results of this randomised, controlled trial in a group of 203 vulnerable older persons did not show that the mobile alarm system, the Butler, had an added value compared to the usual home-based alarm. The frequency of going outside in the intervention group was not different at any time point, compared to the control group. Regarding the secondary outcomes, FOF, feeling unsafe and QoL, no significant differences were found between the intervention and control groups. The trend of feeling less afraid of falling at 1-month follow-up in both groups did not persist for the remainder of the study period.

Several explanations can be given for the results of our study. First, there were many dropouts in both groups, especially in the intervention group. Previous research has shown that the recruitment of older, vulnerable persons for clinical...
trials is challenging\textsuperscript{12,13}, and it is an even greater challenge to keep older persons in a trial. Although not significant, dropouts from the intervention group were, at baseline, more afraid of falling than the participants who completed the study. It is conceivable that the participants who were most afraid of falling did drop out. These persons, however, did not participate long enough to show the potential benefits of a mobile alarm in feeling safer outside. Second, older persons feel barriers to using new technologies.\textsuperscript{10} A high educational level, a high income and good health offer good conditions for overcoming these barriers.\textsuperscript{10} It is promising for the future that the number of older people is growing who are happy with new technology once they start using it.\textsuperscript{10} It is important that the development of technology for older people be based on the perspective of the users, who should be engaged in all parts of the process.\textsuperscript{11} New technology should therefore be tailor-made and carefully introduced.\textsuperscript{12} Third, the results could have been influenced by serious weather conditions. The second part of this trial was characterised by extreme winter conditions, with very low temperatures, snow and ice. This coldest Dutch winter in 20 years did have great influence on the frequency of going outside in this part of the trial. Finally, it appeared that some of the participants in the intervention group did not take the mobile alarm outside with them at all times. This omission might have been the result of some perceived user-unfriendliness with the Butler. Also, QoL seemed not to be influenced positively by the mobile alarm system. Most older people evaluate their quality of life on the basis of social contacts, dependency, health, good neighbourhood standards, family relationships, material circumstances and social comparisons.\textsuperscript{17,18} Because QoL depends on various physical, psychological, functional and social aspects, it is not likely that QoL is positively influenced by the use of a mobile alarm alone. We did not find an explanation for the increase in the number of times the intervention group used the home-based alarm during the trial period, compared with the six months before the trial period. We cannot explain why their behaviour changed.

Despite these disappointing results, we believe that this trial is, in terms of the age of the participants, their frailty and the study size, unique for its kind. Little research has been undertaken on mobile safety alarm systems. Although feasible
methods are available for monitoring the activity patterns of older people, these methods have not been applied on a large scale.\textsuperscript{13} The first project concerning mobile safety alarms, the SAFE-21 project, was conducted in the mid-1990s.\textsuperscript{14} These first mobile safety alarms were simple but useful in fulfilling basic user needs.\textsuperscript{15} Within the MobiHealth project, supported by grants from the European Union, new services and applications in the area of mobile health were developed.\textsuperscript{16} Within this project, a mobile safety alarm was tested by Melander-Wikman et al. (2007). In this study, older persons’ experiences with a mobile alarm and their reasoning about safety and mobility were described, but an increase in mobility was not an outcome measurement as such. The results of this pilot study showed that participants experienced the mobile safety alarm as a tool for being active and mobile, as well as a way to maintain self-determination and have control over their lives.\textsuperscript{15} Mobility, as prerequisite for participation in society, is a dimension of this empowerment. A mobile alarm can be seen as an aid to continuing one’s participation in society.\textsuperscript{15}

Under the MobiHealth system, two studies on mobile alarm systems were performed in Sweden.\textsuperscript{7,15} Although the number of participants was rather small in these studies (n=5 and n=9), and participants were not randomised, the results of these studies showed that a mobile alarm was experienced as a tool for being active and mobile and for having control over one’s own life.\textsuperscript{7,15} These results could not, however, be confirmed by our study. In the first study on mobile safety alarms, performed in Sweden\textsuperscript{7}, older persons were actively involved in the development of the mobile alarm, as they were in testing a prototype.

There are a number of methodological limitations to our study. First, participants who were interested in taking part in this trial had to subscribe actively. This requirement might have resulted in a biased group of participants. It is possible that older persons who hardly ever go outside would not subscribe for this study. Generalisation of our results to the whole population of older persons may therefore not be appropriate. The participants in our study were, however, not drawn from the general population. Also, we chose to recruit participants among older persons who were interested in using a mobile alarm. In contrast, in
the studies on mobile alarms performed in Sweden, the participants were representatives of various senior citizens’ organisations. Perhaps these were older persons with affinities for technology, explaining the more positive results. Next, despite efforts to enhance data completeness, study dropouts resulted in missing data. Study dropout persons were more likely to be frailer, both physically and mentally, at baseline. Dropouts were, however, comparable in both groups, limiting their effects on the comparability of the intervention group and the control group.

Several recommendations for research and practice may stem from this study. For future research, studies aimed at testing new technologies in a population of older persons may need to consider involving older persons in the development and testing of this new technology. Technology is a part of life, and in general, no insurmountable impediments exist for older people using new technologies.\(^\text{10}\) The size and weight of the Butler was, however, one of the main reasons for dropouts, which might have been prevented if older people had been given the opportunity to test a prototype. Second, in planning health-promoting studies, investigators need to be aware of the number of older people they should screen and of different strategies to retain the target population. Patient recruitment is recognised as one of the most difficult aspects of the study process, especially for research involving elderly subjects.\(^\text{17,18}\) Key approaches are the timely screening, identification and approach of eligible patients and careful evaluation of whether the intervention is appropriate for the target population and setting.\(^\text{19}\) Little research has been performed on risk factors for attrition in studies with longitudinal phases. A systematic review by Chatfield et al. showed that individuals who drop out for reasons other than death tend to be older or more cognitively impaired.\(^\text{20}\) Although not statistically significant, our study also showed that, in both study groups, dropouts tended to be older and more cognitively impaired than the participants who completed the study.
In summary, we did not find an added value from the mobile alarm system, compared to the home-based alarm. Participants with a mobile alarm showed no increase in the frequency of going outside, and also, FOF, feelings of unsafety and QoL did not seem to be influenced positively by the Butler. However, more research is advocated on mobile alarm systems, with a focus on the recruitment of older persons and on retaining them in studies.

ACKNOWLEDGEMENT
The authors thank Frits Boelens from the ATA Alarm Service for his advice and assistance during this study and Lina Jager for her help in collecting the data.
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FIGURE 1
PARTICIPANT FLOW DIAGRAM

Participants using a home-based alarm invited by mail to participate
n=656

Interested in participating and contacted by telephone
n=245

411 did not return reply card

42 excluded (not interested anymore)

203 randomised

100 randomised to Butler

29 withdrew from FU 1 month
11 not interested anymore
7 Butler too big/heavy
2 too complicated
1 wanting to go outside after 5:00 PM
6 not coming outside
1 thought to get mobile phone
1 thought technique didn’t work

FU 1 month n=71
n=64 received for FU 1 month
n=16 missing data FU 1 month

3 withdrew from FU 2 months
1 Butler too big/heavy
2 not interested anymore

FU 2 months n=68
n=79 received for FU 2 months
n=21 missing data FU 2 months

8 withdrew from FU 4 months
2 deceased
4 Butler too big/heavy
1 area not big enough

FU 4 months n=60
n=74 received for FU 4 months
n=25 missing data FU 4 months

2 withdrew from FU 6 months
1 stay in nursing home
1 not interested anymore

FU 6 months n=58
n=70 received for FU 6 months
n=30 missing data FU 6 months

103 randomised to care as usual

14 withdrew from FU 1 month
5 because not receiving Butler
4 not interested anymore
1 personal circumstances
1 bound to wheelchair
3 change in health status

FU 1 month n=89
n=73 received for FU 1 month
n=16 missing data FU 1 month

1 withdrew from FU 2 months
1 deceased

FU 2 months n=88
n=74 received for FU 2 months
n=14 missing data FU 2 months

7 withdrew from FU 4 months
1 because not receiving Butler
4 not interested anymore
1 admission to nursing home
1 deceased

FU 4 months n=81
n=68 received for FU 4 months
n=13 missing data FU 4 months

4 withdrew from FU 6 months
1 deceased
3 not interested anymore

FU 6 months n=77
n=73 received for FU 6 months
n=4 missing data FU 6 months

FEAR OF FALLING IN OLDER PATIENTS

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### TABLE 1
**BASELINE CHARACTERISTICS* OF PARTICIPANTS (n=203)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group (n=100)</th>
<th>Control group (n=103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>80.9 (9.1)</td>
<td>81.2 (9.3)</td>
</tr>
<tr>
<td>Number female (%)</td>
<td>77.0</td>
<td>78.6</td>
</tr>
<tr>
<td>≥2 chronic conditions (%) †</td>
<td>80.0</td>
<td>76.7</td>
</tr>
<tr>
<td>Chronic dizziness with falling (%)</td>
<td>18.0</td>
<td>22.3</td>
</tr>
<tr>
<td>Impaired vision (%)</td>
<td>22.0</td>
<td>16.5</td>
</tr>
<tr>
<td>Impaired hearing (%)</td>
<td>16.0</td>
<td>20.4</td>
</tr>
<tr>
<td>Cognitive impairment (%)</td>
<td>47.0</td>
<td>44.7</td>
</tr>
<tr>
<td>Fall incident in last 3 months (%)</td>
<td>21.0</td>
<td>20.4</td>
</tr>
<tr>
<td>Difficulty walking (%)</td>
<td>82.0</td>
<td>77.7</td>
</tr>
<tr>
<td>Use of walking aid (%)</td>
<td>72.0</td>
<td>77.7</td>
</tr>
<tr>
<td>Going outside (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Daily/once a week</td>
<td>93.8</td>
<td>93.2</td>
</tr>
<tr>
<td>- Once a month/never</td>
<td>6.1</td>
<td>6.8</td>
</tr>
<tr>
<td>- Wanting to go outside more often (%)</td>
<td>35.0</td>
<td>25.2</td>
</tr>
<tr>
<td>Mean VAS-Fear of Falling 1 to 10 (SD)‡</td>
<td>5.3 (2.9)</td>
<td>5.4 (2.9)</td>
</tr>
<tr>
<td>Mean VAS-Feeling Unsafe 1 to 10 (SD)‡</td>
<td>4.5 (2.3)</td>
<td>4.3 (2.2)</td>
</tr>
<tr>
<td>Not going outside because of feeling unsafe (%)</td>
<td>10.0</td>
<td>12.6</td>
</tr>
<tr>
<td>Self-rated health status (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Very good</td>
<td>1.0</td>
<td>1.9</td>
</tr>
<tr>
<td>- Good</td>
<td>18.0</td>
<td>17.5</td>
</tr>
<tr>
<td>- Fair</td>
<td>61.0</td>
<td>59.2</td>
</tr>
<tr>
<td>- Bad</td>
<td>17.0</td>
<td>23.8</td>
</tr>
<tr>
<td>- Missing</td>
<td>3.0</td>
<td>4.8</td>
</tr>
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</table>

* Characteristic presented in percentage or mean and standard deviation (SD)

† Chronic conditions = diabetes, stroke, heart failure, cancer, pulmonary diseases, urine incontinence, arthritis, osteoporosis, dizziness, prostate disorders, depression, anxiety, dementia, heart attack

‡ VAS= Visual Analogue Scale
### Table 2
**Percentage change in frequency of going outside**

<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Control group</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td><strong>Difference baseline and FU 1 month, %:</strong></td>
<td><strong>Difference baseline and FU 1 month, %:</strong></td>
<td></td>
</tr>
<tr>
<td>- going outside more</td>
<td>- going outside more</td>
<td>5.6</td>
</tr>
<tr>
<td>- no change</td>
<td>- no change</td>
<td>83.3</td>
</tr>
<tr>
<td>- going outside less</td>
<td>- going outside less</td>
<td>11.1</td>
</tr>
<tr>
<td><strong>Difference baseline and FU 2 months %:</strong></td>
<td><strong>Difference baseline and FU 2 months %:</strong></td>
<td></td>
</tr>
<tr>
<td>- going outside more</td>
<td>- going outside more</td>
<td>5.3</td>
</tr>
<tr>
<td>- no change</td>
<td>- no change</td>
<td>65.8</td>
</tr>
<tr>
<td>- going outside less</td>
<td>- going outside less</td>
<td>28.9</td>
</tr>
<tr>
<td><strong>Difference baseline and FU 4 months, %:</strong></td>
<td><strong>Difference baseline and FU 4 months, %:</strong></td>
<td></td>
</tr>
<tr>
<td>- going outside more</td>
<td>- going outside more</td>
<td>6.8</td>
</tr>
<tr>
<td>- no change</td>
<td>- no change</td>
<td>67.1</td>
</tr>
<tr>
<td>- going outside less</td>
<td>- going outside less</td>
<td>26.0</td>
</tr>
<tr>
<td><strong>Difference baseline and FU 6 months, %:</strong></td>
<td><strong>Difference baseline and FU 6 months, %:</strong></td>
<td></td>
</tr>
<tr>
<td>- going outside more</td>
<td>- going outside more</td>
<td>4.3</td>
</tr>
<tr>
<td>- no change</td>
<td>- no change</td>
<td>47.8</td>
</tr>
<tr>
<td>- going outside less</td>
<td>- going outside less</td>
<td>47.8</td>
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Figure 2
Effects of the Mobile Alarm on Primary Outcome (n=203)

<table>
<thead>
<tr>
<th></th>
<th>baseline June-July-August</th>
<th>1 month August-September-October</th>
<th>2 months September-October-</th>
<th>4 months November-December-</th>
<th>6 months January-February-March</th>
</tr>
</thead>
<tbody>
<tr>
<td>cases daily/weekly</td>
<td>93,8</td>
<td>93,1</td>
<td>92,4</td>
<td>90,7</td>
<td>77,9</td>
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<tr>
<td>controls daily/weekly</td>
<td>93,2</td>
<td>98,6</td>
<td>94,7</td>
<td>89</td>
<td>82,6</td>
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<tr>
<td>cases monthly/never</td>
<td>6,1</td>
<td>6,8</td>
<td>7,6</td>
<td>9,3</td>
<td>22,1</td>
</tr>
<tr>
<td>controls monthly/never</td>
<td>6,8</td>
<td>1,4</td>
<td>5,3</td>
<td>8,2</td>
<td>17,4</td>
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### Table 3
**Effects of the Mobile Alarm on Secondary Outcomes, Fear of Falling and Feelings of Unsafty**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VAS for fear of falling, mean (sd):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- baseline</td>
<td>100 5.3 (2.9)</td>
<td>102 5.4 (2.9)</td>
<td>0.80</td>
</tr>
<tr>
<td>- FU 1 month</td>
<td>84 4.2 (2.8)</td>
<td>73 4.8 (2.8)</td>
<td>0.18</td>
</tr>
<tr>
<td>- FU 2 months</td>
<td>79 4.9 (3.0)</td>
<td>74 4.4 (2.7)</td>
<td>0.33</td>
</tr>
<tr>
<td>- FU 4 months</td>
<td>74 5.4 (3.1)</td>
<td>68 5.3 (3.3)</td>
<td>0.82</td>
</tr>
<tr>
<td>- FU 6 months</td>
<td>70 5.3 (3.1)</td>
<td>69 5.1 (2.8)</td>
<td>0.63</td>
</tr>
<tr>
<td><strong>VAS for feelings of unsafety, mean (sd):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- baseline</td>
<td>100 4.5 (2.3)</td>
<td>100 4.3 (2.2)</td>
<td>0.49</td>
</tr>
<tr>
<td>- FU 1 month</td>
<td>84 3.8 (2.7)</td>
<td>71 3.7 (2.7)</td>
<td>0.80</td>
</tr>
<tr>
<td>- FU 2 months</td>
<td>79 3.6 (2.8)</td>
<td>75 3.8 (2.8)</td>
<td>0.63</td>
</tr>
<tr>
<td>- FU 4 months</td>
<td>53 3.9 (2.6)</td>
<td>45 3.7 (2.3)</td>
<td>0.67</td>
</tr>
<tr>
<td>- FU 6 months</td>
<td>70 3.8 (2.5)</td>
<td>67 3.6 (2.6)</td>
<td>0.64</td>
</tr>
</tbody>
</table>

VAS = Visual Analogue Scale
CHAPTER 7

REFERENCE LIST


