A randomized trial comparing digital video disc with written delivery of falls prevention education for older patients in hospital

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Title

A Randomized Trial of Digital Video Disc (DVD) Compared to Written Delivery of Falls Prevention Education for Older Patients in Hospital.

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ABSTRACT

Objectives: To compare the effectiveness of Digital Video Disc (DVD) and written workbook delivery of falls prevention education on older hospital patients’ self perceived risk of falls, perception of falls epidemiology, knowledge of prevention strategies, and motivation and confidence to engage in self protective strategies. To compare the effect of receiving either education approach versus no education on patients’ perception of falls epidemiology.

Design: Randomized trial (DVD versus workbook) with additional quasi-experimental control group.

Settings: Geriatric, medical and orthopaedic wards in Perth and Brisbane, Australia.

Participants: One hundred (n=51 DVD, n=49 workbook) hospital inpatients aged ≥60 in the randomized trial (mean age 75.3 ± 10.1) and 122 in the control group (mean age 79.3 ± 8.3).

Intervention: Participants randomly assigned to receive identical educational material in either DVD or workbook delivery of falls prevention education. Control group received usual care.

Measurements: Custom designed survey addressing elements of the Health Belief Model of health behaviour change.

Results: Participants randomized to DVD delivery had a higher self perceived risk of falling (P=.04) and higher levels of confidence (P=.03) and motivation (P=.04) to engage in self protective strategies compared to participants who received the workbook. A higher proportion of participants who received either form of the education provided “desired” responses compared to control group participants across all knowledge items (P<.001).
**Conclusion:** Delivery of falls prevention education via DVD achieves key changes in parameters likely to impact upon successful uptake of falls prevention messages in the hospital setting, relative to a written workbook.

**Key words:** accidental falls, hospital, inpatients, prevention, education
INTRODUCTION

Falls are a frequent adverse event when older people are hospitalized. Rates of between 2.2 and 21.4 falls per 1000 patient days,\(^1\)-\(^5\) are reported. Up to 30% of these falls cause injury,\(^2\)-\(^4\),\(^6\) and falls are a preventable cause of mortality.\(^6\) In-hospital falls are associated with reduced quality of life, increased disability, prolonged hospital stay and resource use and increased risk of institutionalization.\(^7\)-\(^9\) Recent meta-analyses have concluded there is insufficient evidence that any hospital falls prevention programs reduce falls incidence or the number of fallers.\(^10,11\) A majority of studies included have been multi-factorial intervention programs which have yielded inconsistent results.\(^3,5,12,13\) Compositional differences between intervention programs examined may explain some of this variability, indicating the need to identify individual elements / interventions that could be used to prevent falls.

Patient education has been frequently cited as one component of multi-factorial falls prevention interventions,\(^3,5,12,13,14\) though has not been examined as a single intervention in this setting. A subgroup analysis found patient education to be the most effective component of a successful multi-factorial intervention.\(^14\) Inconsistency in description of content, theoretical framework and mode of delivery in studies to date, has also created uncertainty regarding the optimal provision of education.

Health care providers commonly use written information as a low cost approach to providing patients with health information. However, advances in DVD-based technology and lower costs have made this approach a viable alternative or complementing delivery strategy. DVD presentation can be useful for patients who have auditory and / or visual learning styles and may assist patients who have low functional health literacy to understand the content that is
being shared.\textsuperscript{15,16} Lower levels of health literacy are more common in older people.\textsuperscript{17} Although numerous public health studies have investigated the effect of education in other patient populations,\textsuperscript{18,19} there is little research that has compared approaches for providing health information to older adults, and no research in the context of falls prevention.

The purpose of this study was to compare the effectiveness of DVD versus written delivery of falls prevention education material, on patients’ self perceived risk of falls, perception of falls epidemiology, knowledge of falls prevention strategies and confidence and motivation to engage in self protective strategies. This study also sought to determine whether providing either form of education versus no education affects the proportion of patients who have an accurate perception of the risks of falls and fall-related harm they face in hospitals.
METHODS

Design
This study was a two-group randomised trial (DVD versus written education) with a quasi-experimental control group (no education). The control group data was collected during phase 1 and the randomized trial was conducted during phase 2. The participant flow through the study is shown in Figure 1.

Participants and setting
Hospital patients from the geriatric assessment and rehabilitation unit or orthopaedic unit of the Princess Alexandra Hospital (PAH), Brisbane, Australia, or the restorative unit or medical ward of the Swan Districts Hospital (SDH), Perth, Australia were recruited into the randomized trial component of this study during December 2007 and January 2008. The control group was recruited from the same geriatric assessment and rehabilitation unit of the PAH during 2007.

The acute wards at both hospitals admit older patients undergoing short stay surgical and medical treatment for a variety of conditions such as chest infections or fractures. The sub acute rehabilitation wards admit older patients undergoing rehabilitation for a variety of geriatric conditions.

Patients were not approached to participate in this study if they were under 60 years of age, had a Mini Mental State Examination score of less than 24 out of 30, were medically unstable, had previously participated in the study, or had severe vision or hearing deficits that prevented engagement with the education material.
**Intervention**

Participants received the falls prevention education privately by their bedside, either by DVD or written delivery and were allowed up to one hour to study the materials. Participants in shared rooms received the education and survey administration at separate times with privacy screens in place. Investigators facilitated optimal engagement with the education by adjusting environmental or individual elements, including seated position and application of visual or hearing aids.

**Materials**

The DVD and workbook were designed to contain identical content. This content was based on the Health Belief Model (HBM) framework for understanding health-related behaviours.\(^\text{21}\) Examination of patient behaviour following education is a well developed concept in the area of behavioural sciences and the HBM is one of the most widely used frameworks for predicting preventative health behaviours.\(^\text{18,21}\) The HBM assumes that a person will undertake a protective health behaviour if four conditions are met. First, patients perceive they are at risk of contracting the negative health outcome. Second, patients perceive that contracting the negative health outcome will adversely affect their health / welfare. Third, patients consider that the costs incurred through undertaking the health behaviour are outweighed by the costs of not undertaking it. Fourth, there is a cue or prompt for the person to take action.

The content addressed falls prevention specifically to i) inform patients of the risk of falls and fall-related harm such that patients have an accurate perception of the risks they face, ii) inform patients of falls prevention strategies that they could undertake within the hospital setting, iii) foster patient belief that they could successfully undertake falls prevention
strategies and that if undertaken, their risk of falling will reduce, iv) provide a cue for action by facilitating patient planning to undertake falls prevention strategies. Information presented under aims i) and ii) was based upon local data and data presented in previous research.6, 22, 23

The workbook design followed the recommended principles of design for written patient education materials.24 Specifically; a 20 point Arial font and 1.5 line spacing was used. Twenty four A4 pages (matt paper) contained a mixture of text, colour graphics and photographic images taken from the DVD footage. The readability level of the workbook was assessed using the SMOG readability formula25 as 7th grade level.

The DVD was 14 minutes in duration and content was identical to the workbook. Words were spoken verbatim and the manner of speech followed recommended principles for oral communication.24 The narration was spoken at a moderate pace with several breaks to allow the participant time to process the information presented. DVD footage presented an older patient model simulating falls risk behaviours and falls prevention strategies with a mixture of video footage, still shots and written captions. The DVD material was edited using Pinnacle Studio Plus version 9 software and played on a portable Digital Video Disk Player (Dick Smith Electronics, Australia, Model: DSE 9” G7137) with a 9 inch screen and accompanying stereo headphones (Sony Australia, Model: MDRXD 100).

**Outcome Measures**

A custom designed survey was developed to determine whether the education differentially addressed the four specific aims of providing the education. The wording of items is listed in Table 1. Items 1-3, 5, 7, 9, 11, 14, examined whether the intervention informed participants
of the risk of falls and fall-related harm such that participants had an accurate perception of
the risks they face. These items took two forms; those asking participants if they now felt
more aware of these issues and those posed as “knowledge” items, which reflected the
information presented. Self-perceived awareness items were Likert scaled (strongly agree to
strongly disagree). Knowledge items employed both open response (item numbers 4, 6, 8)
and multiple choice (for item numbers 10 and 12) response formats. Items 13, 14 and 15
examined participants’ motivation to reduce their risk of falling in general.

The remaining items focused on strategies to prevent falls in hospitals. Participants were
asked to name strategies that they thought they could use to prevent themselves from falling
and then to identify the strategy that they thought would be most effective in reducing their
risk of falls (items 16, 17 and 18). Items 19, 20 and 21 examined participants’ confidence
and motivation to undertake the strategy identified in item 18.

**Procedures**

Ward staff identified patients who met inclusion criteria and asked if they were willing to be
approached by researchers. Amenable patients were provided with written and verbal project
description prior to written consent being sought.

Participants in the control group had knowledge items (4, 6, 8, 10, 12) administered at their
bedside. All participants received usual ward orientation and ad hoc falls prevention advice
from staff on admission but control group participants did not receive any specific falls
prevention education from the investigators and were not involved in any randomization
procedures.
Participants in the randomized trial were each asked item 1 (self-perceived risk of falling) before being allocated into DVD or workbook group. The allocation was performed by the interviewer who opened an opaque sealed envelope with the participant’s study identification number on it and group allocation within. Group allocations were determined by a computer generated random number sequence that was produced by the senior investigator (TH) who was not involved in recruitment or data collection. The investigators (AH & SM) were blinded to the allocation sequence until after participants provided consent and had completed the baseline assessment of self-perceived risk of falls. Participants were not blinded to the knowledge of the education approach that they received and the investigators conducting assessments were aware of participants’ group allocation during the post-intervention assessment.

The investigators administered all survey items including a repeat assessment of self perceived risk of falling, (item 2) immediately after the education.

**Statistical Analysis**

Baseline characteristics of participants were compared between groups using parametric statistics (independent group t tests) for continuous normally distributed data, logistic regression to compare groups across nominal characteristics and negative binomial regression to compare the rates of falls (6 months prior to admission and during admission prior to survey) between the groups.

Comparison between groups on outcomes with ordinal scaling was conducted using Wilcoxon ranksum tests. Responses to knowledge items in both intervention groups and in the control group were converted to binary data on the basis of being “desired” or
“undesired” answers. “Desired” answers were those that reflected the data presented in the educational material. For multiple choice format items, the exact answer was required. For example, item 12 “where do falls occur most frequently in hospitals?” related to the section in the educational material that told participants that most falls occur by the bedside. Therefore, the response “bedside” was the only “desired” response. For items that used continuous outcome scaling, a +/- 5% tolerance threshold was allowed for.

Logistic regression analyses were then employed to determine if the proportion of respondents who provided “desired” responses was different between the DVD group and the workbook group and between the control group and education groups (DVD and workbook) combined. Alpha level for significance was set to $P < .05$ for all comparisons.

Data management and analysis was completed using Stata version 10.0 software (StataCorp, Texas). All analyses were based on an intention-to-treat principle.

**Ethics**

This study was approved by local hospital ethics committees and The University of Queensland Medical Research Ethics Committee. The study was registered with the Australian Clinical Trials registry- registration number (ACTRN1260800064303).
RESULTS

Demographic characteristics of participants were broadly similar between the two intervention groups (DVD n=49, mean age 74.5±9.7, workbook n=51, mean age 76.1±10.5; \( P=.76 \)) and between the intervention groups (n=100) and the control group (n=122), although the mean age of the intervention group was four years younger than the control group (intervention 75.3±10.1, control 79.3±8.1; \( P<.001 \)). There were 57 females (57%) in the intervention groups [DVD n=31 (63%), workbook n=26 (51%)] and 68 females (56%) in the control group and MMSE scores were similar between the intervention groups [mean (score 0-30) DVD 27.1±2.0, workbook 27.8±3.0; \( P=.22 \)] and between intervention and control groups [mean (score 0-30) intervention 27.4±2.4, control 26.8±2.2; \( P=.94 \)]. There were 21 falls prior to enrollment in the intervention group (DVD n=7, workbook n=14; \( P=.42 \)) and 15 falls in the control group (intervention n=21, control n=15; \( P=.39 \)).

A high proportion of patients approached in both phases of the study consented to participate, and there were no withdrawals (Figure 1). Patients (n=16) who declined to participate most commonly cited lack of interest in the study. Education sessions were completed in full by 92% (n=45) of the DVD group and 92% (n=47) of the workbook group. There was no significant difference between the groups in their self perceived risk of falls (item 1) prior to the education (\( P=.72 \)).

Between-group comparisons for items employing Likert scaling response approaches are presented (Table 1). There was no significant difference between groups in self-perceived risk of falls following the education (items 1 and 2, Table 1 \( P=.70 \)). However, there was a within-group increase in the self perceived risk of falls in the DVD group after education
compared to before the education ($P=.04$), while the change within the workbook group was not significant ($P=.18$), though the median response for each group changed from “Disagree” to “Undecided” with inter-quartile ranges remaining the same.

Comparisons between the intervention groups and between the control group and intervention groups combined, for knowledge items (items 4, 6, 8, 19, 12) are presented in Table 2. A higher proportion of participants who received either form of the education provided “desired” responses compared to control group participants across all knowledge items (Table 2; $P<.001$).

All 49 participants who watched the DVD identified a strategy that they thought would be effective in reducing their risk of falls (item 16). Of participants who were provided the workbook, 49 of 51 identified a strategy. The most commonly identified strategies were: planning ahead before moving (DVD n=9, workbook n=17), waiting for help (DVD n=6, workbook n=6), asking for help from staff (DVD n=9, workbook n=5) and avoiding dizziness by getting out of bed slowly (DVD n=6, workbook n=5).

Participants in the DVD group identified a secondary strategy (87%, n=43/49) more frequently than those in the workbook group (68%, n=35/51) [odds ratio (95% CI), $P$-value: 3.28 (1.16, 9.26), $P=.025$].

Participants in the DVD group were more motivated ($P=.03$, item 13; Table 1) and confident ($P=.03$, item 19, Table 1) in their ability to attempt strategies for reducing their falls risk in hospital following education.

There were no adverse effects attributable to the education or the survey administration.
DISCUSSION

This trial evaluated different modes of delivery (DVD versus workbook) of falls prevention education to older patients’ using the HBM education framework. The DVD mode of delivery demonstrated superiority to the workbook approach in modifying patients’ perceptions, belief and knowledge in several key areas identified in our adapted model. These areas included self-perceived knowledge of risk, motivation to avoid falls, knowledge of falls risk and of falls prevention strategies. These findings indicate that the DVD mode of delivery is likely to be superior to the workbook approach for delivery of in-hospital falls prevention education based upon a HBM education framework.

Participants who watched the DVD had a significantly increased self-perceived risk of falling after the education. Previous studies using the HBM confirm that an increased self perceived risk of threat predicts change in future planned behaviour,21,26,27 therefore it was not surprising to also find that participants who watched the DVD were also more motivated to engage in falls prevention activities. Providing education via either approach generated “desired” responses to knowledge items more frequently than in the control group where no education was provided. Hence it is apparent that providing patient education, particularly through a DVD approach, may equip older patients to avoid in-hospital falls, assuming that the HBM is an appropriate framework for preventing in-hospital falls.

The relative superiority of the DVD approach may be explained by principles of adult education which postulate that visual and auditory modes of education may be more effective in conveying information, as these modes allow for different learning styles of participants.15,16,28 The results of this study are consistent with those from a previous trial in
a similar population where patients undergoing rehabilitation for fractured femurs also demonstrated improved uptake of education following video and audio CD and printed delivery compared to usual care. These findings form an emerging evidence base indicating that DVD-based education should be employed in the hospital setting, particularly for older adults. Although this trial compared the DVD approach to a workbook approach, it is likely that providing both approaches simultaneously may also prove to be feasible.

The representativeness of the study sample to the wider patient population is limited as only patients with basic cognition intact participated and it is possible that patients more amenable to receiving falls education may have participated. People with cognitive impairment have been found to be at a higher risk of falls in the hospital setting, however were excluded from the present study due to the cognitive requirements of responding to the survey items. The study did not investigate the effect of the education on actual uptake of falls prevention strategies and on subsequent falls rates after exposure to the intervention though this is currently being evaluated in a longitudinal randomized trial.

Provision of health education to older adults using multi-media approaches may result in superior uptake of information influencing patient perceptions and motivation to participate in protective health strategies, culminating in better health outcomes. Further work is indicated to identify the most clinically effective and economically efficient approaches to providing health information for this population and to determine whether improved knowledge uptake translates to reduced incidence of falls. DVD-based technologies now offer a feasible alternative or adjunct to traditional written approaches to providing health information and should be considered for use in clinical practice.
ACKNOWLEDGEMENTS

The authors thank staff and patients at PAH and SDH and staff at The University of Queensland, School of Health and Rehabilitation Sciences.

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**Author contributions**

THa was principally responsible for the project conception and design of multimedia. AH was responsible for project organisation, intervention provision and data collection at the SDH site and SM at the PAH site. AH and THa were principally responsible for the data analysis and drafting of the manuscript. SM, KH, THo, SB, DO, CB contributed to project conception and design, interpretation of data analysis and critical revision of the manuscript.
REFERENCES


Table 1  Survey Items Measuring Participants’ Perceptions.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item wording</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Undecided</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>No Response</th>
<th>Wilcoxon P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I think that I will fall over at some point while I am here in hospital (pre-intervention)</td>
<td>2/7</td>
<td>11/8</td>
<td>9/2</td>
<td>16/25</td>
<td>11/8</td>
<td>0/1</td>
<td>.72</td>
</tr>
<tr>
<td>2</td>
<td>I think that I will fall over at some point while I am here in hospital (post-intervention)</td>
<td>10/9</td>
<td>9/9</td>
<td>10/9</td>
<td>13/18</td>
<td>7/6</td>
<td>0/0</td>
<td>.70</td>
</tr>
<tr>
<td>3</td>
<td>I feel I am now more aware of how often people fall over in hospital.</td>
<td>26/22</td>
<td>21/24</td>
<td>1/2</td>
<td>1/3</td>
<td>0/0/0</td>
<td>0/0</td>
<td>.13</td>
</tr>
<tr>
<td>5</td>
<td>I feel I am now more aware of what proportion of falls result in injury.</td>
<td>26/11</td>
<td>18/26</td>
<td>1/12</td>
<td>4/2</td>
<td>1/0</td>
<td>0/0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>7</td>
<td>I feel I am now more aware of what proportion of falls are witnessed by hospital staff</td>
<td>22/14</td>
<td>20/24</td>
<td>5/9</td>
<td>2/4</td>
<td>0/0</td>
<td>0/0</td>
<td>.05</td>
</tr>
<tr>
<td>9</td>
<td>I feel I am now more aware of when falls occur in hospital</td>
<td>35/23</td>
<td>13/25</td>
<td>1/3</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
<td>.007</td>
</tr>
</tbody>
</table>

Data presented are DVD group response frequency / Workbook group response frequency
<table>
<thead>
<tr>
<th></th>
<th>Statement</th>
<th>Score</th>
<th>Score</th>
<th>Score</th>
<th>Score</th>
<th>Score</th>
<th>Score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>I feel I am now more aware of where falls occur in hospital</td>
<td>32/27</td>
<td>13/16</td>
<td>3/6</td>
<td>1/1</td>
<td>0/1</td>
<td>0/0</td>
<td>.001</td>
</tr>
<tr>
<td>13</td>
<td>I am currently highly motivated to prevent myself from falling.</td>
<td>39/31</td>
<td>10/18</td>
<td>0/1</td>
<td>0/1</td>
<td>0/0</td>
<td>0/0</td>
<td>.03</td>
</tr>
<tr>
<td>14</td>
<td>The DVD/book material has made me feel more motivated to prevent myself from falling than what I was before I saw it</td>
<td>29/18</td>
<td>12/24</td>
<td>7/5</td>
<td>1/4</td>
<td>0/0</td>
<td>0/0</td>
<td>.04</td>
</tr>
<tr>
<td>15</td>
<td>I feel I am now more aware of strategies that I can use to prevent myself from falling.</td>
<td>23/15</td>
<td>19/28</td>
<td>7/6</td>
<td>0/2</td>
<td>0/0</td>
<td>0/0</td>
<td>.12</td>
</tr>
<tr>
<td>19</td>
<td>I am confident that I can attempt this strategy (referring to strategy identified in item 18*).</td>
<td>33/23</td>
<td>16/27</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
<td>0/1</td>
<td>.03</td>
</tr>
<tr>
<td>20</td>
<td>I am confident that if I attempt this strategy that I will reduce my risk of falling (referring to strategy identified in item 18*).</td>
<td>24/21</td>
<td>21/26</td>
<td>4/2</td>
<td>0/1</td>
<td>0/0</td>
<td>0/1</td>
<td>.59</td>
</tr>
<tr>
<td>21</td>
<td>I now intend to attempt this strategy during my hospital stay to reduce my risk of falling (referring to strategy identified in item 18*).</td>
<td>30/26</td>
<td>18/24</td>
<td>1/0</td>
<td>0/0</td>
<td>0/0</td>
<td>0/0</td>
<td>.41</td>
</tr>
</tbody>
</table>

* Item 18) Which strategy do you feel will be the most effective in reducing your risk of falls?
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item wording</th>
<th>DVD</th>
<th>Workbook</th>
<th>Odds ratio</th>
<th>Control</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(n=49)*</td>
<td>(n=51)*</td>
<td>(95%CI), P value</td>
<td>(n=122)*</td>
<td>(95%CI), P value</td>
</tr>
<tr>
<td>4</td>
<td>For every 100 patients in this ward, how many do you think would fall before</td>
<td>29 (59)</td>
<td>18 (35)</td>
<td>2.65 (1.18, 5.96),</td>
<td>24 (19)</td>
<td>4.08 (2.23, 7.45),</td>
</tr>
<tr>
<td></td>
<td>they leave?</td>
<td></td>
<td></td>
<td>.01</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>6</td>
<td>For every 100 falls that occur on this ward, how many do you think would</td>
<td>11 (22)</td>
<td>10 (20)</td>
<td>1.18 (0.45, 3.11),</td>
<td>5 (4)</td>
<td>6.22 (2.25, 17.18),</td>
</tr>
<tr>
<td></td>
<td>result in a physical injury, such as a bruise, a laceration, a head injury,</td>
<td></td>
<td></td>
<td>.72</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>or even a broken bone?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>For every 100 falls that occur on this ward, how many do you think are</td>
<td>10 (20)</td>
<td>8 (16)</td>
<td>1.37 (0.49, 3.84),</td>
<td>3 (2)</td>
<td>8.70 (2.48, 30.51),</td>
</tr>
<tr>
<td></td>
<td>witnessed by a hospital staff member</td>
<td></td>
<td></td>
<td>.54</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>10</td>
<td>When do falls occur most frequently in hospitals?</td>
<td>43 (88)</td>
<td>40 (78)</td>
<td>1.97 (0.66, 5.82),</td>
<td>49 (40)</td>
<td>7.27 (3.85, 13.72),</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.22</td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>12</td>
<td>Where do falls occur most frequently in hospitals?</td>
<td>32 (65)</td>
<td>27 (53)</td>
<td>1.67 (0.74, 3.74),</td>
<td>34 (27)</td>
<td>3.72 (2.12, 6.53),</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.21</td>
<td></td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Data are n (%) with desired response.
Figure 1. Participant flow Through the Study

Phase 1

Enrolment

Patients meeting initial screening criteria (n=131)

Excluded
Not interested in study (n=9)

Included in study (n=122)

Phase 2

Patients meeting initial screening criteria (n=109)

Excluded
Not interested in study (n=9)

Included in study (n=100)

Measurement*

Item 1

Randomization

Allocation

Intervention

Measurement*

Items 4, 6, 8, 10, 12.

Analysis

Included in analysis (n=122)

*See tables 1 & 2 for wording of survey items.