# **Master Thesis**

# Process evaluation of a washing-without-water cross-over trial

A qualitative study

Student: B. (Bart) Langenveld

Student number: 5666988

Education: Master student Clinical Health Services, Nursing Science, University of

Utrecht

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Supervisor: Prof. Dr. S. (Sandra) M.G. Zwakhalen, Health Services Research, University

of Maastricht

Course docent: Dr. L.M. (Marlies) Schrijvers

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# LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

BL Bart Langenveld, student Clinical Health Science

COREQ Consolidated Criteria for Reporting Qualitative Research: a 32-item checklist

FG Drs. F. Groven

FvH Fransje van Heiningen, student Clinical Health Science

IC Informed Consent

SZ Prof. Dr. S. (Sandra) M.G. Zwakhalen

WWW Washing-Without-Water

# Abstract Process evaluation of a washing-without-water trial

Background: An alternative bathing method with disposable wash-gloves shows some advantages compared to traditional bathing. However, in a review with a focus on traditional bathing of immobile patients no significant difference was found in patient-related variables with washing-without-water (www). Therefore, a cross-over trial was developed in a skills-lab setting to compare the effects on quality of www with traditional bed bathing. To gain more insight into process elements, an evaluation was performed alongside the cross-over trial.

*Aim:* The aim was to provide insights into process experiences with first-year students of the Bachelor School of Nursing, who were exposed to the www cross-over trial.

*Method:* A qualitative study was conducted using semi-structured interviews with 14 first-year students and two observers. All interviews were audiotaped and transcribed verbatim into NVivo-11 software. A framework adopted by Saunders (2005) guided data into a thematic approach, in which four compromised process elements were assessed, namely: reach and recruitment, dose delivered and received, context, and fidelity.

Results: Main findings show that the recruitment procedure was not successful enough to obtain a required number of students in the trial study. Participated students were satisfied with the constructive design of procedural activities. Students assessed similarities of the skills lab setting within the reality of practice.

Conclusion: This process evaluation provides useful information to guide future research into new bathing methods with nursing-students. The complexity can be found in the recruitment of eligible students, effective strategies must be considered within the perception of these younger participants.

Recommendations: Improving recruitment can be achieved through research integration into planned school activities with presentations in smaller student groups. Also, the adoption of social media to involve students for participation is an area worth exploring.

Keywords: Process evaluation, qualitative, bed baths, traditional bath, washing without water

#### Samenvatting Procesevaluatie van een wassen zonder water trial

Achtergrond: Een alternatieve wasmethode met wegwerp wasdoekjes laat enkele voordelen zien in vergelijking met het traditioneel wassen. In een review met de focus op traditioneel wassen van immobiele patiënten werden echter geen significante verschillen waargenomen in patiëntgerelateerde variabelen met het wassen zonder water (www). Zodoende werd een cross-over trial ontwikkeld om het effect van www te vergelijken met het traditioneel wassen op bed. Voor meer inzicht in de proceselementen werd naast de cross-over trial een evaluatie uitgevoerd.

Doel: Het doel was inzicht te krijgen in proceservaringen bij eerstejaars studenten aan de Hogeschool Verpleegkunde, die werden blootgesteld aan de www cross-over trial.

Methode: Een kwalitatief onderzoek met semigestructureerde interviews werd uitgevoerd onder 14 eerstejaarsstudenten en twee observatoren. Alle interviews werden woordelijk getranscribeerd in NVivo-11. Een raamwerk overgenomen van Saunders (2005) ondersteunde de thematische aanpak, waarbij vier gecomprimeerde proceselementen werden beoordeeld op bereik en werving, geleverde- en ontvangen dosis, context, en betrouwbaarheid.

Resultaten: De bevindingen tonen aan dat de wervingsprocedure niet voldoende aansloot om het vereiste aantal studenten te krijgen in de trialstudie. Deelnemende studenten waren tevreden met het constructieve ontwerp van de procedurele activiteiten uit de trial. Studenten beoordeelden de skills labsetting als een geloofwaardige weerspiegeling van de praktijk.

Conclusie: Deze procesevaluatie biedt bruikbare informatie voor toekomstig onderzoek naar nieuwe wasmethode bij verpleegkundestudenten. De complexiteit kan worden toegekend aan de werving van in aanmerking komende studenten. Effectieve strategieën moeten in beschouwing worden genomen binnen de perceptie van deze jonge participanten.

Aanbevelingen: Een verbeterde werving kan mogelijk worden bereikt door onderzoek te integreren in geplande schoolactiviteiten, met presentaties in kleinere studentengroepen. De adoptie van social media om studenten te betrekken is een verkenning waard.

Kernwoorden: procesevaluatie, kwalitatief, wasbeurt op bed, traditioneel wassen, wassen zonder water

# Introduction

Personal hygiene assistance, like bathing, is an essential basic nursing care activity that impacts the patients quality of life and quality of care experiences<sup>(1–4)</sup>. Basic nursing care activities are viewed internationally as essential in patient centered care<sup>(4,5)</sup>. Bedridden patients are often unable to perform personal hygiene independently because of acute illness or chronic debilitation, so a traditional bed bath with water and soap is needed to ensure hygiene<sup>(6)</sup>. Previously reported downsides of traditional bed bath are related to stress and resistance in patients, and negative physical consequences and high time-consumption for nursing staff<sup>(5)</sup>. Also, this traditional bathing using water, soap and towel drying has been reported to remove natural skin oil, leading to skin dryness and increase vulnerability for microbial invasion<sup>(7)</sup>.

An alternative bathing method using disposable wash-gloves has been developed, introduced, and is becoming common practice in bedridden patients<sup>(8)</sup>. Most wash-gloves products are disposables made of soft fibers containing skin friendly and quickly vaporizing cleaning with caring lotions, designed for hygiene and optimal skin care<sup>(8)</sup>. This method called washing-without-water (www) claimed to offer several advantages compared to the traditional bed bath<sup>(9)</sup>. A study by Slaughter et al. (2017) showed that disposable wash-gloves supposedly cost less than traditional bed baths, increase patient satisfaction and improve professional staffs ergonomic aspects<sup>(10)</sup>.

In a systematic review with a focus to traditional bed bathing of immobile patients, no significant positive effects were found for patient-related variables (e.g. skin lesions, resistance during bathing) with www<sup>(9)</sup>. However, positive aspects were reported about skin dryness, skin hydration, bathing completeness, nurse satisfaction and bed-bath care quality. Following these results, more insight is required into the overall value of users to allocate www in their own experiences.

For that reason, a www cross-over trial has been developed by Groven et al. A randomized cross-over trial conducted in a skills lab setting with students of the Bachelor Nursing School. The trial compared the effects on quality of www with traditional bed bathing, connected with caregivers' time needed for bathing<sup>(10–12)</sup>. For general information see figure 1.

To obtain more insight in process elements in relation to the program of the www cross-over trial, a process evaluation was performed alongside this trial<sup>(13,14)</sup>. A process evaluation is a method to analyze whether the planned activities of the trial have been executed as planned in a uniform way, and describes the experiences of those exposed to the intervention<sup>(14)</sup>. A process evaluation also describes whether the target population (here nurse-students) is actually exposed to these activities as planned, their experiences and to identify causal pathways according local needs and contexts<sup>(14,15)</sup>. This evaluation plan provides more insights into the facilitators and barriers of the followed cross-over trial study<sup>(13)</sup>. Therefore, the results in this article can have a valuable input for next investigations<sup>(14)</sup>.

#### Aim

The aim of the present study was to provide insights into process experiences with first-year students of the Bachelor School of Nursing, who were exposed to the www cross-over trial. This was done by assessing the following process elements, namely<sup>(16,17)</sup>:

- (1) The reach and recruitment, and the motivation for involvement;
- (2) The participants' engagement with the delivered and received intervention aspects;
- (3) Research context and how this affected the intervention coverage;
- (4) Program fidelity and uniformity during implementation.

#### Method

### Study design

A qualitative process evaluation was conducted in a formative manner, using semi-structured face-to-face interviews with nurse-students<sup>(18)</sup>. A qualitative design was chosen because it provides insights into the process elements and students' experiences with the delivered cross-over trial. This aspect of data is particularly appropriate when relevant variables have not been identified, a criterion especially salient to the www-topic, where so little research has been performed<sup>(18)</sup>. The motivation for formative use of assessment was the possibility to make adjustments in the original trial plan if necessary<sup>(19)</sup>. In addition, fieldnotes were taken and two follow-up interviews were conducted with observers who participated in the trial study. Within this study, the COREQ reporting guidelines were used in the presentation of method and findings<sup>(20)</sup>.

#### Population and domain

The domain of this process evaluation was the University of Applied Science, Bachelor School of Nursing. The Bachelor School of Nursing trains students for classification level six, who are widely employable in different settings concerning health promotion, recovery, growth and development, and preventing disease, disorder or limitations<sup>(21)</sup>. Participants in this study were first-year students with minimal experience in clinical practice. As a training, students practiced bed washing in a skills-lab setting prior to the research. Students were eligible if they received instructions about the www cross-over trial and actually participated in this trial study. In addition, they had to be able to speak and understand Dutch adequately. Students who finished the www cross-over trial prematurely were excluded from participating in this evaluation study.

#### Study parameters

The study parameters were based on the adopted process evaluation framework of Saunders (2005), a framework with six elements, namely: reach, recruitment, dose delivered, dose received, context, and fidelity<sup>(16)</sup>. This framework guided the thematic approach in this study to support the organizing conceptual thinking<sup>(17)</sup>. Data from the interviews and

observations were used to examine these process elements in a compromised way of four elements that were defined as follow:

Reach and recruitment: these themes entail the degree in which the students participated in the www cross-over trial. It refers to the procedures used to approach and attract students at an individual level, and it includes the process of maintaining students' involvement.

Dose received and delivered: these themes describe students' satisfaction with the received program, and interaction with the investigator. It reflects all elements of the intervention that were delivered. Furthermore, the themes describe the time spent to perform the intervention. Context: this theme was relevant in identifying meaningful factors from the environment that could affected the performance of the intervention (e.g., those setting factors that could influence the interaction between the students).

Fidelity: this theme was defined as the degree to which the protocol of the trial study was implemented as intended.

#### Data collection

A convenience sample was recruited in April 2018 by the present researcher (BL). In total, 27 first-year nurse-students were eligible to participate. The interviews lasted, as expected, a maximum of 30 minutes and were audiotaped after receiving written informed consent. To ensure a balanced proportion of interviews from both trial groups, first the trial group nurses left the skills room. In this way, each student out of the two trial groups had an equal chance of being admitted for an interview. A topic list (See Appendix 1) based on the study parameters reach and recruitment, dose delivered and received, context, and fidelity, guided the interviews and observations to ensure accuracy and relevant coverage areas according to the aim of the research<sup>(22,23)</sup>. This ensured a consistent process between the interviews with a maximum amount of data<sup>(22,24)</sup>. For validation, the topic list was based on literature reviews and expert knowledge, and then reviewed by the principal investigator (SZ)<sup>(25-27)</sup>. A pilot interview was conducted to supplement the list of subjects and to promote interviewing skills<sup>(22,28)</sup>.

With a one-week trial interval, data collection was carried out over several days. The interviews were conducted in a quiet room at the university shortly after the cross-over trial to capture recent experiences, and prevent loss of data to avoid recall bias<sup>(29,30)</sup>. Each student was informed about the purpose of this study and invited both orally and in writing. The interviewer explained the study in more detail and answered questions<sup>(30)</sup>. Each interview started with a general question in the broad area of the study to put students at ease and to follow first thoughts<sup>(28)</sup>. The subsequent interview questions focused on the elements of Saunders (2005)<sup>(16)</sup>. Afterwards, students got the opportunity to contact the researcher if they wanted to share additional information. Fieldnotes were taken during observations throughout all phases of the trial study. The observations were conducted to describe the setting and capture detailed social dynamic information<sup>(15,28,29,31,32)</sup>.

To ensure transparency, fieldnotes were written in a Word format guided by the parameters. For triangulation, the researcher interviewed two observers to complement the information from previous interviews and observations. A composite topic list guided these interviews (See Appendix 2).

# Data analysis

Data from the interviews and observations were analyzed using a thematic approach in which the pre-defined study parameters, according to the elements of Saunders (2005), were used<sup>(16,33)</sup>. Information was analyzed at two moments, where emerging aspects from the first data was used to inform the research process and adjust the topic list with supplementary questions for the second round of data collection<sup>(28)</sup>. Verbatim transcripts of spoken language were generated from audiotaped interviews with students and observers. Data from the observers was used as a supplement for verification. Additionally, the fieldnotes and methodological memos were transcribed.

The transcribed interviews and observations were uploaded into NVivo-11 (Melbourne, Australia) with the support of an expert (FG)<sup>(34)</sup>. Two researchers (BL, FvH) independently coded three transcripts and found essential similarities. Disagreements were discussed until consensus was reached. To check internal validity of the transcriptions, three students received a summary of their interview for feedback and were asked if they recognized the results<sup>(13)</sup>.

The coded citations lead to a set of descriptive topics per transcript<sup>(13)</sup>. Thoughts and considerations were highlighted as a memo in NVivo-11 (Melbourne, Australia). In the refinement process, descriptive summaries were discussed with the research team, and transformed to clarify their relationship with the central question<sup>(29)</sup>. All advices and notes, insights and motivations, were stored in a logbook during all phases of the research<sup>(22,28)</sup>. Findings were organized and categorized into themes based on their similarity in meaning<sup>(22,28)</sup>. The results were checked with a critical view for correctness in a peer review by the research team (SZ, FG). Finally, refinement continued until all thematic process elements were depicted with illustrative quotes from the complete dataset.

#### Ethical considerations

This study is in accordance with the Declaration of Helsinki; ethical approval was obtained from the Institutional Review Board. The protocol of the full cross-over trial has been registered in Clinical-trials.gov: TC6972.

All students were informed verbally and in writing about the process evaluation. If eligible, students provided written consent to participate in this study. In the students' interest, it was made sure that they did not feel forced in any way to participate<sup>(35)</sup>. Students had the option to stop their participation at any time. There were no obligations for participation that could affect student-teacher relationship<sup>(35,36)</sup>.

#### Results

Results are described below using four themes comprising in pre-defined study parameters reach and recruitment, dose delivered- and received, context, and fidelity. They illuminate the main experienced facilitators and barriers of the cross-over trial <sup>(13)</sup>. Eventually, 14 students completed the interviews. A total of eight students out of the trial nurse group and six students from the patient group were interviewed. Recruitment continued until saturation of data was achieved, and no new information was emerged <sup>(4,13,28)</sup>. Of the participated students, twelve were female and two were male. The age ranged from 17 to 24 years. Background data of the participants are presented in Table1.

#### Reach and recruitment

# Documentation of the priority target audience

The proportion students participated in the trial study was 12% of all first-year nurse-students of the University. These students had limited experiences in washing people, the washing procedure was only practiced recently at school during skills training. An important motivation for participating in the trial study was the possibility to be engaged in scientific research, and the extra learning opportunity to wash other people.

"I had never participated in such a scientific research, I wanted to try that one time. Moreover, I also should wash people during my internship, and this is a good exercise." Ref.1

Students argued that their presence was a self-conscious voluntary participation. A single student felt some degree of dependence influenced by school performance, and indicated that:

"I think, it has been my choice. But, if you show you are motivated to follow things alongside your regular lessons, that this is also conducive to your study. Imagine, I would get a problem or did not pass a test and you have a motivation meeting with the team leader?" Ref.8

# The planned and actual recruitment procedures

At the first stage, students were invited on blackboard (BB) to participate in lecture due to the trial study, which was given at three different moments. Next, multiple invitations for study participation were posted on BB and mail with instructional videos about washing patients. Sign-up sheets were circulated during lectures and lessons, and could be delivered any time at a previously indicated place.

"This was explained in a lecture by the principal investigator (FG). Further information I found in the mail, which has informed myself well. In the mail, there were a few videos about washing people." Ref.2

#### Barriers for recruiting individuals

Participation was scheduled as an extra activity beside planned school time. Because of this, interviewed students reported several reasons for not participating in the trial study. They labeled the priority in time fulfillment, and already achieved 'special activity' hours as most common reason. Because absent students were not interviewed, this is a mindset that can only be discussed.

"This is a period that most people have to learn for their tests, maybe it is not the right time to do this research. Perhaps the research should take place during a school day, so we do not have to come to school only for research." Ref.4

# Procedures and initiatives used to encourage involvement

Concerning the number of students that registered their participation for the trial study, multiple activities were undertaken as an extra stimulus to engage students. Namely, students were allowed to register their participation with extra 'special activity' hours. Teachers were asked to promote the study with students during lessons, and extra mails were sent to the students as a reminder. This constant connection with the target population was found as an extra motivation for participation.

"Later, it became clear that there were not enough registrations, then the 'special activity' hours were increased." Ref.2

"In our classroom, the tutor came with pictures: "look, this is the research you can participate." Ref.11

#### Barriers to maintaining involvement

At the same time, some students indicated that they do not always follow the information by mail. More substantive information about the study by social media or presentations in smaller groups could provide a personal attention to talk about the study.

"Outside the mail and lecture, put something on social media because we are students." Ref.10

"I think, if someone comes to tell in class, that makes sense. That also give more impression." Ref.4

### Dose-received and dose-delivered

#### Reactions on organization

Regarding the organization, most students assessed the regulation and procedures of the trial study as unambiguously and solid. Fundamentals like the detailed organization and reliability were complimented by the students.

"It was very clear, I really noticed that. At school it is really chaos, but this was really wow! They say where I should go, what I'm going to do, who I am, what I play and what time I have to be present. It was actually very, very clear." Ref.2

In line with this, students called the personal connection from the principal investigator (FG) and keeping in touch with the target population as an extra motivation.

"I really liked the lecture, it is one of the nicest I had. Because, he (FG) was so personally involved, with those photos, etc." Ref.8

#### Procedure resources

With regards to the protocols of the different washing methods, most students indicated the applicability as useful and meaningful. Before this study, students were not aware of the fact that washing someone is so protocolled. However, a small improvement was appointed to make the protocol a bit more compacter.

"It was all step by step, for example; put the sheet down, pull out the patients' pants, and take of the socks. Sometimes it was wide written, I could not find where I was. It was a lot of text, that could be shorter, a bit more compacter." Ref.7

#### Delivered components of the cross-over trial

All students described a structured approach in the performance of the trial study. This was emphasized by the observers present in the skill rooms.

Students performed the different washing methods according the trial protocol guideline. Some students explained they skipped turning, because the trial group 'patients' were ambulant enough to sit up straight. Furthermore, the intimate zones were also passed during the washing method.

"I followed the paper of the protocol. I have done it exactly in order of the steps on the paper, nothing at all skipped. I really did exactly what was told in the video and was written on the paper, all steps were explained." Ref. 3

#### Time findings in performance of washing

Most participated students experienced a time inequality while performing the different washing methods. Both trial groups 'nurses' and 'patients' indicated that washing-without-water took less time and fewer actions were required during the www-method. On the other hand, observers noted that students were less nervous on the second trial day, which could also cause the element of time.

"I found, washing-without-water went very quickly. Because, by washing with water [...] it will take a little longer before you can start anyway." Ref.2

"The second time, I saw a bit more, [...] relaxation. That the students were uncertain the first time, during the second time that was a bit away." Obs.1

#### Context

# Environment influence on outcome

Most students had limited experiences in washing other people and felt insecure, they estimated themselves as unexperienced. In their opinion, it made it somewhat forced in the execution of the intervention of the trial study. Observers confirmed the youthfulness and uncertainty of students in social interactions 'because they talked more than necessary', but were pleased with the professionalism in which they accomplished the procedure.

"The only thing is, we were washed by first-year students. They do not have that much experiences yet, and do not know very well how exactly to wash someone. [...] Perhaps it would be better to be washed by a third- or fourth-year student, who would know better what to do." Ref.8

Students reaction about matching the practical situation in skills lab setting varied. Students could imagine that the design and arrangement of the rooms corresponded with practice. But there was some lack of confidence among students in their own performance to wash people. Students suggested to add senior students or/and a simulation patient, to make it more realistic.

"Yes, maybe a real simulation patient... that you really see: 'this is more realistic, than a student who washes'. That you let someone or more people come and then do the intervention." Ref.4

# **Fidelity**

#### Implementation accuracy of the protocol

The www cross-over trial was achieved as initially planned in the study protocol, no changes were made in design, model, and program of delivery. Instructions of the trial study were implemented by a qualified competent interventionist, with multiple experiences in the promotion and execution of research. In addition, monitoring of the delivery of the trial study was established with observations by independence observers and a research team.

"He has shown himself as a very flexible researcher (FB) [...]. It has gone flawlessly, the small problems were immediately solved, so.... very practical." Obs. 2

#### Discussion

This qualitative study reports the results of the process experiences of first-year bachelor nursing-students who participated in the www cross-over trial. Main findings show that, despite the extensions, the recruitment procedure was not successful enough to obtain the required number of students for an optimal group size. Even though flexibility was required, students were satisfied with the delivery of the trial study that was applied in a constructive and convincing design of procedural activities in the current situation. Concerning the contextual setting, students declare an overlap that corresponds to the reality of practice: they only questioned their own performance in supporting to wash people. Additionally, no adjustments have been made to the procedure, the trial protocol has been delivered according to plan<sup>(17)</sup>. However, some challenges were established in the process of delivery (e.g. difficulty in recruiting students) and will be discussed in the light of current literature<sup>(13)</sup>. Despite the clear information during lectures and many other efforts, findings show low recruitment rates. As in line with other studies, for the success of recruitment multiple program strategies were implemented, where students had equal opportunities to participate (36-38). Given the small group of students in the trial study, probably only the most motivated students participated. This may cause selection bias, because this was probably a selective group. Therefore, generalization possibilities are limited, because this homogenous higher educated student group will likely not be involved directly with basic-nursing care later<sup>(39–41)</sup>. Like the profession profile (2012) describes, these students are more focussed on their careers, which makes this sub-sample not comparable to practice<sup>(41)</sup>. As a recommendation to improve recruitment, this study supports the student proposal and literature advice to integrate research into planned school activities with recruitment presentations in smaller class groups<sup>(42)</sup>. Also, the adoption of social media as an added value to engage students for participation is an area worth exploring. From an ethical point of view, the absence of many students advocates for truly voluntary participation, in which nonparticipants were not pushed<sup>(37)</sup>.

In resulting dose and reach, students indicate the learning value in scientific research and patient care as an important reason for participation. This is debatable, because participation as such provides no guarantee for educational gain<sup>(37)</sup>. However, several studies suggest that students can learn from an experimental situation when students learn about patient care where he or she is a patient himself, like the www cross-over trial<sup>(35,37,43)</sup>. Having a need can be an essential motivator. Wilson et al. (2013) describes that aware participants are motivated to understand the experimental situation, where this situation should enable participants to suggest the research situation in what they need to do to make it look normal<sup>(43)</sup>. This has probably been an essential factor in the reliability of the implementation of the www cross-over trial.

According to the contextual factors found in this process evaluation, students questioned their own performance with the reality of clinical practice. Most students assess the trial

program as an optimal support to their declared degree of inexperience in washing people, with credible reflection of the expected practice. Although students believe in transferability, threats arise from interaction between the treatment variable of interest and the context in which it is delivered to the participant population concerned<sup>(43–46)</sup>. Therefore, students suggest a more flexible approach with senior students or the presence of simulation patients. This corresponds with literature in designing a 'real world' model, with flexible approaches that relate the simulation scenario to the real clinical problems<sup>(47)</sup>. To create the real clinical setting is a challenge, and caution is always necessary when generalizing specific work to other contexts<sup>(44,48)</sup>.

This study has several strengths. Due to the individual interviews in this study, this approach appears to be a good decision on practical issues. As Gibson (2007) reports, conducting a focus-group with young people can be quite a challenge on a methodological and practical level, e.g., requiring a certain number of people<sup>(49)</sup>. Furthermore, the use of the methodological framework by Saunders (2005) provided key features in guidance and development for a comprehensive evaluation plan<sup>(14,16,50)</sup>. To prevent bias in the interpretation, process data were analyzed before the outcome data of the cross-over trial were known<sup>(16,51)</sup>. Other strengths are the utilisation of independent analysts (because of the objective approach), and the use of a qualitative computer program (systematic analysis) with support of an expert<sup>(13,22)</sup>.

Due to the aim of this process evaluation, a limitation is that only participating students of the trial study were interviewed. Information from non-participating students about, for example, how to improve recruitment procedures, could been an added value<sup>(13)</sup>. Furthermore, the interviewed students gave relatively a lot of product information instead of process information. This may be caused by the fact that it contained a product innovation they were unfamiliar with. Another limitation concerns the moment on which the interviews were performed. Because this evaluation was performed alongside the cross-over trial, first interviewed students had not completed the entire intervention (they only had one condition; www or traditional washing). As a result, information may have been missed.

The formative use in this study provides a model for organizing conceptual thinking about key process elements in the www cross-over trial, and can yield valuable input for the development and implementation during follow-up studies<sup>(16,19)</sup>. This information can then be used to inform researchers and policymakers<sup>(13,17,22,28)</sup>. For future research, it is recommended to use a summative evaluation approach. The summative use involves making a judgement about the extent to which the trial study was implemented as planned and reached the intended participants<sup>(16)</sup>.

#### Conclusion

This process evaluation provides meaningful findings in reach and recruitment, dosereceived and -delivered, context, and fidelity associated with the execution of the www crossover trial. The adapted methodology in this study offered a stepwise approach to provide credible process related explanations that can support the trial outcomes. The complexity of the trial study can be found in the recruitment of eligible participating students. For effective strategies, methodological and contextual issues must be considered and associated within the perceptions of these younger participants. Integration of intervention in existing school activities and lectures in small groups, without students feel threatened are valuable. Despite these considerations, the findings provide an appropriate input for further research to improve quality of care, that contributes the individual needs and quality of life of patients.

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#### Table and box

# Figure 1

### Box1. Summary of the www cross-over trial

The washing-without-water (www) trial was designed as a randomized cross-over trial. This program was offered at nurse students in a skills lab setting. The trial took place in two days with an interval of one week at the University of Applied Science. The trial study was initially planned within practical bathing lessons in which all first-year students were instructed in different bed bathing methods, but later performed as an extra activity beside planned school time.

#### Recruitment and randomization

Students were recruited in close collaboration with the coordinators of the educational institution. They were invited on their digital study environment (Blackboard) for lectures to inform about the trial study. Students received an information letter about the procedure, and were given the opportunity to ask questions about the trial. They could register using sign-up sheets which returned immediately or within one week after lecture at an indicated place. Afterwards, multiple invitations to participate in the www cross-over trial were sent by mail and placed on the digital study environment.

After students had registered, they were randomly assigned per computer to either the trial nurse group or patient group. Then consequently received or provided both the intervention, being a bed bath with a www-product, and the traditional bad with water and soap. Before the start of the cross-over trial, participants received by mail information about time and place of the bed-baths. Students were instructed in both methods, www (wash-gloves) and the traditional bed bath. Students in the patient group were wearing underwear or swimsuits during washing.

Table1.

Table 1 Participant characteristics

Students					
Interview nr	Age	Sex	Ethnic background	Nurse-group	Patient-group
P1	18	F	Dutch		x
P2	21	F	Dutch	X	
P3	21	M	Iran		X
P4	19	F	Dutch		x
P5	18	F	Dutch	X	
P6	18	F	Dutch	х	
P7	18	F	Dutch	х	
P8	19	F	Dutch	X	
P9	17	F	Dutch		x
P10	17	F	Dutch		x
P11	24	F	Curação	х	
P12	17	F	Dutch	X	
P13	18	M	Dutch	х	
P14	19	F	Dutch		X

Abreviations: F female, M male

# Appendix 1

#### Interviews

Interviewvragen HBOV student

#### Introductie

Ik ben Bart Langenveld, student Verplegingswetenschappen aan de Universiteit Utrecht. Ik doe een evaluatieonderzoek voor mijn afstudeerproject naar het 'wassen zonder water'. Om een beter beeld te krijgen welke elementen hierbij een rol spelen wil ik je graag interviewen. In dit onderzoek is het van belang hoe jij 'het wassen-zonder-water' hebt ervaren en hoe deze interventie werd uitgevoerd. Jij kunt mij wellicht informatie geven die belangrijk is voor de verdere ontwikkeling van het wassen op bed. Ik wil het interview graag opnemen, zodat ik het kan verwerken voor mijn onderzoek.

Het interview zal ongeveer 20 minuten duren. Als je problemen of vragen hebt tijdens het interview mag je dit gewoon aangeven. De antwoorden worden anoniem verwerkt, alle informatie is alleen bedoeld voor dit onderzoek.

Zijn er nog vragen voordat we beginnen, of is alles duidelijk?

Tenslotte wil ik vragen of je akkoord gaat als ik het interview opneem?

# Achtergrondinformatie

- Leeftijd
- Geslacht
- Nationaliteit

# Openingsvraag

Vertel eens hoe je het wassen van/door een ander persoon hebt ervaren?

#### Werving

- Waarom heb je besloten deel te nemen aan het onderzoek 'wassen zonder water'?
   Wat was de stimulans om mee te doen?
- Op welke manier werd je gevraagd om deel te nemen aan dit onderzoek?
- Was je bij de informatiebijeenkomst aanwezig en hoe duidelijk was het college?
   Zo nee, hoe ben je aan de informatie gekomen?
- In hoeverre was je deelname aan dit onderzoek vrijwillig?

# **Topics:**

- Obstakels/ barrière
- o Belangen

# Betrouwbaarheid geleverde informatie

- Welke informatie heb je gekregen over 'het wassen zonder water', voorafgaand aan vandaag?
- Was de informatie die je kreeg over het onderzoek duidelijk? Zo nee, is dit van invloed geweest op de uitvoer van de interventie?
- Heb je informatie gemist? En zo ja, welke?

Zou je dit willen toelichten/ Geef eens een voorbeeld.

# **Geleverde en ontvangen interventie**

- Beschrijf hoe het uitvoeren van de interventie verliep?
- In hoeverre heb je het onderzoek uitgevoerd zoals van te voren was afgesproken?

  Ben je afgeweken van het protocol en waarom heb je dat dan gedaan? (Het is niet erg als je bent afgeweken)

#### Topic:

- o Volgorde
- o Gebruik van materialen
- Tijdsduur (voldoende tijd om handeling uit te voeren conform afspraak)

#### Context

- In hoeverre kon je jezelf goed inleven in de situatie van verpleegkundige/ patiënt? (Die niet in staat is om zichzelf te wassen of die de handeling moet verrichten).
- Toen je het wassen zonder water uitvoerde werd je toe beïnvloed door mensen aanwezig in de ruimte of andere factoren? Zijn er factoren geweest die deze ervaring hebben beïnvloed? (Zaken die belemmerend waren)
- Zijn er omgevingsaspecten geweest die invloed hadden op jouw ervaring met de wasbeurt? Zou je dit willen toelichten?

# Topic:

- o Contact medestudent tijdens de wasbeurt
- (Wat heeft jou niet geholpen bij het uitvoeren van de interventie? Of juist wel?)

# **Afsluiting**

- Wat zijn jouw suggesties om het www-onderzoek te verbeteren? Topic, welke onderdelen vond je goed aan het programma en welke niet?
- Zijn er nog vragen of andere opmerkingen?
- Ga je ermee akkoord als ik je de resultaten uit dit onderzoek toestuur voor feedback of de informatie die je mij hebt gegeven correct is verwerkt?
- Ik denk dat ik genoeg informatie heb. Ik wil je hartelijk bedanken voor de medewerking. Dan zal ik nu het interview officieel beëindigen.

# **Appendix 2**

# Interviewvragen observatoren.

# Openingsvraag:

- Beschrijf eens hoe het uitvoeren van het onderzoek door de studenten verliep?
  - o Wat was je eerste indruk?
  - o Wat viel je op?
  - o Hoe heb je het aspect tijd ervaren?
- In hoeverre werd het onderzoek uitgevoerd zoals van tevoren was afgesproken?
- Wat vond je van de bekwaamheid van de studenten in het uitvoeren van het onderzoek?
  - Konden de studenten de verpleegkundige/ patiënten in de praktijk evenaren?
- Wat was jouw indruk over de motivatie van de studenten?

- Zijn er suggesties om het www-programma te verbeteren?
  - o Werd de praktijk voldoende nagebootst?
- Zijn er factoren die van invloed zijn geweest op het onderzoek?
  - o Belemmerende factoren
  - o Bevorderende factoren
- Is er nog informatie die je met mij wilt delen over het onderzoek wassen zonder water?
- Zijn er nog andere vragen of opmerkingen?