

Project Description
Use of hearing aids
**Development and implementation of a counselling
program for hearing aid users**

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Introduction

Hearing impairment is one of the most common health issues among adults in Western countries. It has been specifically associated with poor physical functioning and decreased self-sufficiency, and known to have detrimental impacts on both physical and mental functioning. The interactions between health conditions, environmental factors and personal factors determine the level and extent of the individual's function, which can lead to significant social inequalities in public health. Socioeconomic status and level of family support are known to influence help-seeking among older hearing-impaired individuals, such that those in greatest need may not receive necessary support services. Although hearing loss can have significant adverse effects on an individual's quality of life, these effects have been found to be reversible through the use of hearing aids. Even short-time use (3 weeks) has been found to improve the emotional and social experience of hearing impaired subjects.

Unfortunately, of the approximately 200 000 people who have been provided with hearing aids in Norway, it is estimated that almost one quarter seldom or never use them. Lack of follow-up support and low motivation may explain why hearing impaired people do not use their hearing aids, but few research studies have addressed these issues. The aim of this study is to evaluate two approaches for increasing hearing aid use, to obtain objective estimates of actual hearing aid use, to identify factors barriers to regular use and to study hearing aid use related to gender and health inequalities.

The study will examine the extent to which follow-up appointments motivate use of hearing aids among people with hearing loss. A randomized controlled design will determine whether hearing aid users who are informed in advance of a follow-up appointment have a different pattern of hearing aid use than a control group that is not pre-informed of the follow-up appointment. For decades, the use of hearing aids has been estimated using questionnaires. In the present study, hearing aid use will be objectively measured in hours per day using the hearing aid's *datalogging*¹ feature. In addition, the study will develop, implement and evaluate a specialized counselling program for hearing aid users. Counselling will be offered to those who use their hearing aid ≤ 1 hour per day. The counselling will utilize a Motivational Interviewing (MI) approach, which is an effective strategy for eliciting a variety of behavioural changes. This study will evaluate the importance of MI-based counselling and follow up support for hearing-impaired people, and the use of datalogging technology will strengthen the evaluation by providing an objective measure of hearing aid use. Difficulties with and barriers to hearing aid use will be documented and analyzed. The research represents pioneering work in the field, and will provide valuable information for improving the rehabilitation services for the growing hearing impaired population.

Background

Prevalence

Hearing loss has an estimated prevalence of approximately 15% of the adult population, and the prevalence is expected to increase to 25% by 2020 (1, 2). It is one of the most common health problems for people aged 65 years and above, and thus, the growing number of hearing-impaired older adults is a natural result of our growing elderly population (3, 4). Findings shows that hearing loss affects 48% of individuals in their 60s, 60% in their 70s, and 90% of people aged 80 years and above (5). The increasing number of elderly in the community will result in a proportional increase in the need for hearing rehabilitation (2, 6).

1) Datalogging automatically stores information about the instrument used, for example, volume changes of operation per day, choice of different listening programs.

Consequences of hearing loss

Hearing loss is one of the most prevalent chronic conditions in the western world (7), but it is still referred to as “the invisible disability” (8) and “a silent disease” (9). Although sensory loss is a natural part of the aging process, it poses considerable and varied problems for the individual (13, 14). Hearing loss adversely affects quality of life (18-21), and impaired physical and mental health is frequent among people with hearing loss (23-25). Hearing impairment has also been found to correlate with a decline in cognitive function (26, 27), a higher level of co-morbidity (21) and a higher risk for nursing home placement (28). Furthermore, health problems are found to correlate with increasing hearing loss (29). Hearing loss may affect the individual's independence and ability to participate socially (15, 16). Inability to hear other people's steps and movements may lead to stress, insecurity and a perceived lack of control (17), thereby having significant effects on mental health.

Many elderly people, in particular, experience difficulty because their hearing loss comes as an extra burden in addition to other health problems. Impaired vision and limited dexterity can also pose challenges to hearing aid use. Clearly, hearing loss is often associated with other health and quality of life issues, which can become more difficult to manage and cope with when one's hearing is also impaired. Health professionals are found to frequently ignore hearing problems among the elderly. This lack of attention to hearing problems could be due to a focus on other diagnoses and sensory problems that frequently appear in older age and are often assessed with higher priority (10-12).

Barriers to Hearing Aid Use

It is estimated that 5 to 40% (30, 34-37) of people with hearing aids seldom or never use them. Various reasons have been proposed for why hearing aids are not being used, including stigma-related reasons (32) and subjective opinion of no need (33). A Norwegian study found that 22% of those with previous hearing aid experience who came for refitting stated they barely used their previous hearing aid (38). However, there is considerable uncertainty about the validity of such investigations, as they are based on the participant's subjective assessments. Studies have shown that many informants overestimate their use of hearing aids, which is often attributed to a “pleasing effect” (39). Reasons for not using one's hearing aid include practical and functional reasons (40), cognitive reasons (41), earmolds that do not fit (34, 42) and poor sound quality (43) among others. Additionally, lack of motivation is a factor of great importance (25, 44). Given that Norway spent nearly N.Kr.300 million fitting people with hearing aids in 2011, or N.Kr. 400 million if expenses for hearing aid repairs and tinnitus generators are also included (51), it is important that people also be provided with adequate support for using them. Otherwise, much of these costs are being wasted.

Follow-up support

The follow-up support of adults fitted with hearing aids is insufficient, as reported in a number of public documents and reports^{2,3,4}. Although 6-month follow-up appointments are often recommended, patients are typically not informed of this, which likely limits the supportive value of the appointments. The high number of under-utilized hearing aids is a sign that the rehabilitation service is not providing adequate support to hearing aid users, which can exacerbate existing health inequalities. Many problems could easily be solved, even by non-professionals. Moreover, it has been argued that the medical and

2) Helsedepartementet og Sosialdepartementet (2002): *Et helhetlig rehabiliteringstilbud til hørselshemmede. Plan for utvikling og organisering av tjenestetilbudet. Handlingsplan.*

3) Sosial- og Helsedepartementet (2001): *Forskrift om habilitering og rehabilitering*

4) Helse – og Sosialdepartementet: Stortingsmelding nr.21 (1998-99) *Ansvar og meistring. Mot ein helskaplig rehabiliteringspolitikk.*

technical focus of audiological follow-up support as traditionally practiced, should instead be a more holistic, multi-disciplinary approach that includes important psychosocial aspects, communication skills and education of significant others (37).

Aim and purpose

The aim of the study is to evaluate two approaches for increasing hearing aid use among adults who need them and to identify barriers to regular hearing aid use. The study will examine the extent to which advanced notice of a 6-month follow up appointment increases use of hearing aids among adults with hearing loss. A randomized controlled design will include an intervention and a control group, and will determine whether hearing aid users who are informed at the time of their hearing aid fitting of a six-month follow-up appointment have a different pattern of hearing aid use than a control group that is not pre-informed of the follow-up appointment.

This study will also develop, implement and evaluate a specialized counselling program for adults fitted with hearing aids. The counselling will utilize a Motivational Interviewing (MI) approach because this technique has been found to be an effective means of achieving behaviour change (45, 46). Subjects who use their hearing aids an average of ≤ 1 hour per day during the first 6 months will be offered MI at the 6-month follow-up appointment.

The effect of the follow up intervention and the counselling program will be evaluated using an objective assessment of hearing aid use (datalogging). These assessments will provide information as to what degree the hearing aids are being used. The study will bring important knowledge into the audiological research field by using this new technology. The datalogging assessment will be conducted 1, 6 and 12 months after the hearing aid is fitted.

Problems related to practical use of the hearing aid will be recorded and categorized for qualitative analysis. This detailed information will be critical to the future development of effective anticipatory guidance materials for the growing population of hearing aid users.

Hypotheses and objectives:

- Test the hypothesis that hearing aids are more frequently used when follow-up appointments are announced at the time the hearing aid is fitted
- Determine the effect of a specialized counselling program based on MI
- Objectively assess hearing aid use using datalogging technology
- Identify problems associated with hearing aid use
- Study hearing aid use related to gender and health inequalities

Method

Participants

The sample will consist of a cross-section of hearing-impaired subjects who are fitted with hearing aids at Lovisenberg Diakonale Hospital. All adults who are referred from an Ear-Nose-Throat (ENT) specialist to the ENT Department for hearing aid fitting will be asked to participate in the project. The participants will receive an information sheet from the Audiologist at their first appointment at the Hearing Center. They will be informed that participating is voluntary and they may at any time withdraw from the project without any impact on further treatment at the hospital. The sample will include first-time users as well as

experienced hearing aid users. The study will be carried out at Lovisenberg Diakonale Hospital.

Inclusion criteria: Age ≥ 20 years. Subjective and objective need for hearing aid

Exclusion criteria: Not being able to communicate in Norwegian.

Subjects will not be excluded based on age, disease or cognitive function.

Statistics

SPSS will be used for statistical analyses (descriptive analysis, correlation analysis, group comparisons, logistic and linear regression). The relationships between hearing aid use in hours per day, subjective experience with hearing aids and reported problems associated with practical and motivational obstacles will be evaluated. Furthermore, the effect of the MI counselling program on subjective reports of problems and objective assessments of hearing aid use (datalogging) will be determined by a pre-post comparison.

Sample size calculations. Our calculations are based on the efficacy variable 'proportion of subjects using the hearing aid less than 1 hour per day', hereafter called p . When comparing p for the two groups in the planned study, with equal numbers of subjects in each group, a chi-square test with 5% significance level will be used. If the true value of p is 25% in group A (intervention group) and 10% in group B (control group), we want the study to have at least 80% power to detect a significant difference in p between groups. It may then be shown that at least 100 subjects must attend the 6-month follow-up appointment in each group.

Considering that many subjects will be quite old, we expect that about 20% of the included subjects will not attend the 6-month appointment. Thus we decided to include 125 subjects in each group. It is also estimated that a minimum of 20 subjects (10% of those attending the 6 month follow up appointment) will meet the criterion for MI (use of ≤ 1 hour per day).

Comment: The effect size for both the randomized controlled trial and the pre-post MI comparison is 15 percentage points. According to clinical experience, we consider this effect size to be realistic. Based on the inclusion criteria and LDS' patient database, it will take approximately one year to include a sufficient number of informants.

Design

Longitudinal designs are emphasized in the project, which includes a Randomized Controlled Design, a Pre-Post Design, and a Descriptive Qualitative Design.

Randomized Controlled Design. Participants will be randomized into an intervention group or a control group at their initial visit to the Hearing Center. Both groups will receive the same treatment with respect to the procedures for hearing aid fitting. However, the intervention group will be informed that a follow-up appointment will take place in six months. The latter group will receive an invitation letter 2-3 weeks before the scheduled appointment.

Pre-Post Design. Objective assessment (datalogging) of hearing aid use will be performed for verification of real-time use. The first assessment will take place when the loan period is over and the hearing aid is assigned, usually one month after the hearing aid is fitted. The second assessment will be at the follow up appointment after six months. The third assessment will be after another six months, or one year after the hearing aid was fitted. Subjects who use their hearing aids ≤ 1 hour per day at the six-month appointment will receive counselling utilizing a Motivational Interviewing (MI) approach. The effect of the counselling will be evaluated in relation to hearing aid use assessed at the 12-month appointment (datalogging).

Descriptive Qualitative Design. At the six-month follow-up appointment, barriers to and problems (practical as well as motivational) associated with use of hearing aids will be identified. The same procedures will be carried out twelve months after the fitting.

Interventions

Follow up appointment. Low motivation is a common explanation for why hearing impaired adults do not use their hearing aids (25, 44). Additionally, it is known that older age and impaired health may lead to additional problems and barriers in the process of getting used to a hearing aid (28, 32, 35). This part of the study will determine whether hearing aid users who are informed in advance of a follow-up appointment have a different pattern of hearing aid use than the control group that is not pre-informed of the follow-up appointment. Further, difficulties with and barriers to hearing aid use will be documented and discussed. Support will be offered when indicated.

Motivational interviewing. Motivational interviewing (MI) will be used to encourage more frequent use of hearing aids among subjects who use their hearing aid for an average of ≤ 1 hour per day during the first 6 months, evaluated at the follow-up visit. MI is a method that is considered to be appropriate to motivate people to engage in certain behaviours, in this context, regular use of a hearing aid. MI can be used as an independent intervention to create interest and motivation, and to prepare a patient/client to change their lifestyle or habits. MI may also be integrated into other treatments to improve the efficacy of the treatment (45, 46). Use of MI is utilized to enhance mental health in young people (47), training and accountability of diabetes patients (48), smoking cessation programs (49) and to encourage increased physical activity in the population (50). MI as a method has been shown to help less motivated patients become more motivated by identifying reasons they might want to engage in behaviour change. The implementation of MI will follow a structured program. Because a conversation based on MI has not been previously developed for hearing aid users, the MI techniques will be adapted for use in this study.

The follow-up appointment and MI will be carried out by trained Educational Audiologists.

Instruments

Demographic and clinical information. Information related to the participant's age, gender, household composition, and degree of hearing loss will be collected using a brief questionnaire (demographic information) and clinic records (audiogram).

EQ-5D. This instrument is applicable to a wide range of health conditions and treatments, and the questionnaire provides a simple descriptive profile and a single index value for health status.

Datalogging. Real time use of hearing aids in hours per day will be assessed by connecting the instrument to the programming tool, NOAH. This tool is currently used for all programming and adjustment of hearing aids. Datalogging automatically stores information about the features used, for example, volume changes of operation per day and choice of different listening programs. In this study, only the usage by hours per day will be read. A data collection form will be developed for the assessment of hearing aid use.

Recording of practical and motivational problems. Problems and barriers associated with hearing aid use will be recorded and categorized by the research team. Among others, physical barriers, motivational obstacles, functional barriers and obstacles related to training and counselling, will be assessed. Findings and statements will be recorded and categorized, and difficulties and problems will be addressed with practical solutions.

Project organisation

The project consists of a multi-disciplinary, international group of clinicians and researchers with extensive experience with project management, innovation and clinical research. Professor Kari J. Kvaerner is an Ear-Nose-Throat specialist with a large clinical practice and many years of experience in epidemiological research. She has published a substantial number of articles in international, peer-reviewed journals, written book chapters and has been leader of several research and innovation projects. Prof.Kvaerner will contribute in the project planning and in writing of articles, and holding the role as supervisor in the postdoctoral research. Cand.Sociol. Steinar Birkeland is Chief Project Advisor at the Hearing Impaired Association (HLF). He will attend to the users' perspective within the project. Karina McGlade-Grando, Cand.Ed., Educational audiologist has many years of practice within audiological rehabilitation. She has further education within cognitive therapy and will participate in the MI counseling program. Caryl Gay, psychologist, PhD, is Research Specialist at University of California, San Francisco and Researcher at Lovisenberg Diakonale Sykehus. She has broad experience in health-related research, expertise in statistical analysis, and an extensive list of publications. Dr. Gay will provide support with the data analysis and publication of findings. Professor Anners Lerdal is Senior Researcher at Lovisenberg Diakonale Hospital, and is employed by the hospital to support and advance the hospital's clinical research environment. He also holds a position as a Professor II at the University of Oslo, Institute of Health and Society. He has extensive experience in international research collaboration and in clinical research within geriatrics and health promotion. His research focus is on examining the relationships between symptoms, behaviour, functioning and quality of life in people with different chronic illnesses. Louise Hickson, PhD is Professor of Audiology, Head of the School of Health and Rehabilitative Sciences, and Co-Director of the Communication Disability Centre at The University of Queensland. Dr. Hickson has published over 140 research articles, books, and book chapters across many areas. She is an elected Fellow and President of the International Collegium of Rehabilitative Audiology and a Fellow of the Audiological Society of Australia. Professor Hickson is also an Editor for the International Journal of Audiology. Jorunn Solheim, Ph.D., Audiologist and Educational Audiologist, has extensive experience in hearing impairment among elderly adults. She is the only Audiologist and one of the few Educational Audiologists in Norway who has obtained a Ph.D. She is currently an active researcher, speaker and clinician within the Audiological field. This project represents a continuation of her previous research and projects. Solheim is the post doctoral candidate, and will serve as the project leader.

Work schedule and plan for publications

Milestones	2014				2015				2016			
	1	2	3	4	1	2	3	4	1	2	3	4
Randomization of the informant group	x	x	x	x								
Data collection (Datalogging)		x	x	x	x	x	x	x	x			
Registration of problems			x	x	x	x	x					
Motivational Interviewing (MI)				x	x	x	x	x	x	x		
Publishing					x	x	x	x	x	x	x	x
Final reports												x

Financing

Application for a three-year postdoctoral project. The budget is specified in the application form.

Relevance and benefit to society

Because the hearing impaired population is growing, there is a significant societal need for appropriate audiological rehabilitation services. To address the problems frequently associated with hearing loss or to prevent such problems from arising, rehabilitation programmes can be utilized as a prophylactic initiative beginning with the onset of hearing loss. The overall aim of all audiological treatment and rehabilitation programmes should be to supply the hearing-impaired individual with a sense of mastery and ability to control hearing problems in daily life, and thereby reduce health inequalities. The proportion of hearing aids that are either put away or seldom used causes not only a problem to the individual suffering from this disability, but also poses a considerable cost-benefit challenge to society at large.

Scientific significance

Given that the number of hearing-impaired persons is increasing, there is a need for appropriate audiological rehabilitation services to alleviate this impairment. The individual's health, resources and social network may affect their motivation for using hearing aids, as well as their ability to seek assistance when needed. Therefore, barriers and problems need to be identified and addressed. The potential benefits of counselling and follow-up support need to be evaluated in order to increase satisfaction and effective use of hearing aids. Furthermore, new technologies now allow for the objective verification of real time hearing aid use. Research projects such as this one will provide some indication of their effectiveness and utility for rehabilitations programs. Finally, the project will be of substantial importance to the effective treatment of hearing loss and to the development of effective rehabilitation programs

Ethical perspectives

The project will be conducted in accordance with the Helsinki Declaration, and is not in conflict with general ethical values. The project is registered by the Norwegian Data Inspectorate and approval is obtained from the Regional Ethics Committee (REC).

Datalogging is a tool that is available in almost all hearing aids that are financially covered by NAV. Hearing aid users are rarely informed that hearing aids can be read electronically, and thus no such information will be given as part of this study. Information relating to data-logging will only be used for statistical purposes and for determining which subjects qualify for the MI counseling.

Dissemination and communication of results

Findings will be communicated to the scientific community at international conferences and in articles published in international refereed journals.

The following publications are planned for publication in internationally accepted journals:

1. Hearing aids – how often are they being used?
2. The effect of advanced notice of follow-up appointments on hearing aid use
3. The effect of counselling on hearing aid use and experience
4. Barriers to and problems associated with hearing aid use
5. The role of motivation in determining hearing aid use
6. Hearing aid use related to gender and health inequalities

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