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Patients' Experience of Motivational Interviewing for Hearing Aid Use: A Qualitative Study Embedded within a Pilot Randomised Controlled Trial

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Abstract

Objective: The aim was to explore patients' accounts with regard to their experience of taking part in a pilot study evaluating the feasibility of conducting a randomised controlled trial (RCT) on the effect of motivational interviewing (MI) on hearing-aid use.

Design: This was a qualitative sub-study embedded in a pilot RCT in NHS in which participants who reported using their hearing aid(s) less than four hours per day were randomised to MI combined with audiology standard care (MISC) (n=20), and standard care alone (SC) (n=17).

A constructivist approach informed by grounded theory was used. 34/37 patients who took part in the pilot RCT underwent in-depth interviews one-month after the interventions. All interviews were audio-recorded, transcribed and analysed thematically.

Results: Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. The themes comprise: (1) additional support, (2) clinician effect, (3) commitment to research, (4) research process, and (5) feeling better about self. Most people highlighted a combination of the themes related to the target interventions provided as well as the themes related to the research participation effect in general.

Conclusion: The provision of hearing aids in the NHS may benefit from adopting a more compassionate patientclinician relationship, additional patient education, and post-hearing-aid-fitting support. These were among the main themes which seemed to have helped people to improve their hearing-aid use.

Finally, this study suggests that the general research participation effect seems to have influenced the levels of hearing-aid use in both groups. Strategies to minimize the research participation effect need to be considered in the design of the future full-scale trials.

Keywords: Motivational interviewing; Hearing-aid; Pilot randomised controlled trial

Introduction

Non-regular use of hearing aids

A meta-analysis showed that hearing aids (HAs) had a medium-tolarge effect on health-related quality of life [1]. Despite this, a recent study in National Health Service (NHS) in the United Kingdom showed that 29% of people (293/1021) do not use their NHS HAs regularly (i.e., use less than 4 hours per day) [2]. The non-regular use was 39.5% for new patients [2]. Previous studies in NHS also reported 43% to 45% for non-regular use [3,4].

In NHS, the choice of HAs is limited. In other countries, patients may have the choice of several HA makes. Despite this, non-regular use in NHS is comparable to that found in other countries: 27% and 58% in two Australian studies [5, 6], 42% in Finland [7], 13% to 31% in

four studies conducted in the USA [8-10], and 25% in Switzerland [11]. For further detail see Aazh et al (2015)[2].

Many patients expect a full restoration of hearing, a "cure" [12]. A phenomenological study suggested that some patients do not regard HAs as acceptable solution but agree to get them mainly to please their partner or family members [13]. Two systematic reviews concluded that stigma of deafness and self-reported hearing difficulties are the main barriers to HA use [14,15].

Why is it important?

Hickson et al [16] suggested that successful HA use requires a minimum of one hour of daily use in order to provide even moderate benefits. In the recent NHS survey, 27% of new patients failed to meet these criteria [2]. 500,000 new patients are fitted with HAs annually across the NHS [4]. The average cost is £350 per person [17]. Therefore, there are approximately 135,000 unsuccessful users annually, corresponding to £47,250,000 waste of NHS funding per year.

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This is a growing concern as it is estimated that there will be about 14.5 million people with hearing impairment by 2031 in the UK, and according to the World Health Organisation hearing loss will be in the top ten disease burdens in the UK by 2030 [18].

Non-use or infrequent use of HAs not only wastes resources but also has other implications: [1] non-use of HAs has been associated with increased risk of "loneliness" among hearing impaired individuals [19]; [2] failure to communicate adequately may adversely affect the nonuser's occupational, educational, leisure, and social activities [20]; [3] partners and family of the non-user may experience activity limitation and participation restriction as a result of their partner's communication difficulties [21]; [4] non-users may not benefit from the learning and reorganization of the auditory cortex associated with consistent hearing-aid use [22], and [5] non-users need to increase their attention, concentration and "listening effort" in order to compensate for their lack of hearing making them more susceptible to mental fatigue in demanding listening situations [23].

Previous studies with regard to improving hearing aid use

There is no proven intervention that can successfully improve HA use in the sub-population of patients with hearing impairment who do not use their HAs consistently. Audiologists typically advise patients to use their HAs consistently throughout the day. This seems to work for majority of patients but not for this sub-population.

Barker et al [24] conducted a Cochrane review on interventions designed to improve HA use and outcome. They included 32 studies. The interventions were mainly focused on education and communication strategies and typically involved 4-6 sessions over a period of 2-3 months (total contact time of 6-10 hours) delivered either in group or distance learning.

Barker et al [24] did not find any evidence of statistically significant effect on HA use or on quality of life measures. Use of HAs often requires a change in behaviour which is a complex process. Simply advising people may not help them to change [25].

What is motivational interviewing?

Motivational Interviewing (MI) [26] is a psychological intervention which is rooted in the client-centred counselling method of Carl Rogers [27] and gives great importance to both understanding a patient's internal frame of mind and exhibiting unconditional positive regard [28]. The key elements of MI are partnership, acceptance, compassion, and evocation [29]. MI involves a flexible and strategic application of some core communication and counselling skills [29] comprising: open questions, affirmation, reflective listening, summarizing, informing and advising with patient's permission.

MI seems to be more effective in people at pre-contemplation and contemplation stages of change [28]. According to the Transtheoretical Model, people move through a series of stages in the process of changing behaviour from being unwilling (pre-contemplation stage), to considering a change (contemplation stage), and to make a change (action stage) [30]. Laplante-Levesque et al [31] assessed the stages of change in patients who failed a hearing screening test. 38% were in contemplation stage and 9% were in pre-contemplation stage, hence not everyone with hearing impairment was ready to use HAs. This could be a contributing factor to non-regular use. Therefore, combining MI with audiology care might improve non-regular use.

There are over 200 randomised controlled trials (RCTs) on the effect of MI on a wide array of problems. Several systematic reviews and meta-analyses support efficacy of MI on adherence to long-term treatments and promoting behaviour change in management of alcohol abuse, addiction, weight loss, diabetes, physical activity, and smoking cessation [32,33].

Summary of the pilot RCT on the effect of MI on hearing aid use

A pilot study was conducted by Aazh (2015) [34] in order to assess the feasibility of conducting an RCT on the effect of MI on hearing aid use.

In summary, this was a pilot single-blind, randomised parallelgroup study where participants were randomly assigned to one of the two groups: MI combined with Standard Care (MISC) (n=20) or Standard Care only (SC) (n=17). SC involved adjusting the hearing aids, and providing instructions and advice. MISC involved MI combined with SC tasks (further details of the interventions are provided later on in the text).

The outcome measurement tools utilized in the pilot RCT were [1] the data logging system on hearing aids which measures the average number of hours that a hearing aid is used per day, and [2] a range of validated self-report questionnaires.

The mean number of hours per day that people used their hearing aid[s] increased from 1 hour per day (SD=1.5) at the baseline to 7 hours per day (SD=3.7) one month after the intervention in the MISC group (n=19) and from 1.3 hours per day (SD=2) to 4 hours per day (SD=3.6) in the SC group (n=17). There was a large between-groups effect size of Cohen's d = 0.98 (95% CI: 0.3 to 1.7) for hearing aid use.

Scores on self-report questionnaires showed improvement in both groups, however the between-groups effect sizes were small. It is very important to establish whether the intervention in the MISC group was consistent with MI and the intervention in the SC group did not involve any aspects of MI. Therefore, all sessions were coded by independent coders using motivational interviewing treatment integrity (MITI 3.1.1) [35]. MISC sessions were coded as consistent with MI while SC did not involve any aspects of MI. See Table 1 for further details with regard to the difference in MITI scores between the MISC and SC groups.

Table 1: The Motivational Interviewing Treatment Integrity Coding System and the Difference between the MISC and SC Groups.

In order to see how well or poorly MI was delivered, all sessions were audio recorded and coded using MITI 3.1.1 [35]. Coding was conducted by an independent coder who is an MI expert and was not involved in any aspect of this research or training of the author.

The MITI is a behavioural coding system that assesses both global scores and behaviour counts within a single review of a random 20-minute segment of an MI session recording. MITI global ratings are in the form of Likert scales of 1 to 5 and an average of 4 is recommended for competency [35]. Global ratings are designed to capture the assessor's overall judgment of the interviewer's behaviour with regard to Evocation, Collaboration, Autonomy/support, Empathy, and Direction. The interviewer's utterances are assessed using behaviour counts. The utterances that receive behaviour codes comprise (1) reflections, (2) questions, (3) giving information, (4) MI adherent (e.g., asking permission, affirmation, emphasize control, support), and (5) MI non-adherent (e.g., advise without permission, confront, direct). Reflection to question ratio of 2, 70% open questions, 50% complex reflections, and 100% MI-adherent behaviours are recommended for adequate MI competency [35].

MI global mean scores for MISC sessions were all at competency level of 4/5 or above. As expected there was a significant difference in MITI global scores between MISC and SC where no MI was provided. The main contrast between MISC and SC sessions was related to the differences in Evocation, Collaboration and Empathy. For Evocation 50% of sessions were ranked as 4 and 50% as 5 in MISC group and 59% ranked as 1 and 41% as 2 in SC group. For Collaboration 40% of sessions were ranked as 4 and 60% as 5 in MISC group and 53% ranked as 1, 41% as 2, and 6% as 3 in SC group. For Empathy 75% of sessions were ranked as 4 and 25% as 5 in MISC group and 76% ranked as 1, 12% as 2, and 12% as 3 in SC group.

Group differences in Autonomy Support were relatively smaller. Twenty percent of the sessions were ranked as 4 and 80% as 5 in MISC group and 12% ranked as 2, 59% as 3, and 29% as 4 in SC group. Finally there was no significant group difference in Direction where 5% of sessions were ranked as 4 and 95% as 5 in MISC group and 100% of the sessions were ranked as 5 in SC group. This indicates that the sessions in both groups were very focused with a clear direction on consistent use of hearing aids.

MISC sessions successfully met the threshold for competency with regard to behaviour counts as measured via MITI. Mean percent open questions was 15% (SD=9) in the SC group and 75% (SD=13) in the MISC group (p<0.001) (based on MITI 3.1.1, 70% or more open questions is needed for acceptable fidelity to MI). Mean percent complex reflections was 38% (SD=42) in the SC group and 66% (SD=8) in the MISC group (p=0.003) (based on MITI 3.1.1, 50% or more complex reflections is needed for acceptable fidelity to MI). Mean percent for acceptable fidelity to MI). Mean percent MI-adherent behaviour was 63% (SD=0.3) in SC group and 95% (SD=0.2) in the MISC group (p=0.0004).

Why an embedded qualitative study is needed?

There is an increased recognition of embedding qualitative research in RCTs in order to gain more insights about the participants' perspectives with regard to the research procedures as well as the processes and intervening factors related to the observed quantitative outcomes [36,37].

Application of RCT design and its post-positivist philosophical underpinnings has been criticised when it comes to assessment of complex interventions [38]. MI is a complex intervention and has several components related to the therapist's attitude, knowledge, skills, and behaviour as well as to the patient's behaviours and attitudes [39,40]. Moreover, behaviour of using hearing aids and its outcome in terms of improving quality of life are complex phenomena which are affected by several personal and environmental factors [12,41].

Postpositivist approach is criticised because its experimental designs such as RCT do not accommodate the open complex reality that is the social world [42]. The RCT design relies on the reductionist approach in order to understand the nature of causality in the social world [43]. It is asserted that any difference in the outcomes between two groups randomly assigned to treatment and control can be proved mathematically that is because of the treatment. This may be the case in a laboratory study in a highly controlled environment but may be difficult to prove if the treatment is a complex intervention and a wide range of known and unknown psychosocial factors might influence the outcome behaviour.

The pilot RCT by Aazh (2015) is one of the unique studies that have shown a considerable amount of improvement in hearing aid use following a counselling-based intervention [24,44]. Therefore, it is important to explore patients' accounts with regard to the factors that helped them to use their hearing aids more consistently as the result of taking part in the study. For instance, it is not clear whether the MI component, the technical adjustments of hearing aids, general patientclinician relationship, or other environmental factors beyond the control of the researcher contributed to the large improvements in hearing aid use observed in the MISC group. Although the participants in the MISC group have achieved greater improvement in their hearing aid use, those in the SC group also made some improvements. It is not clear whether the factors that helped the participants to improve were different between the SC and MISC groups.

This sub-study offers an opportunity to explore participants' feedback of their experiences throughout the research and gain further insight with regard to their perspective on how the interventions influenced their hearing aid use.

Methods

Design

This research comprised a qualitative sub-study embedded within a pilot RCT conducted between May and September 2013 [34]. The design used a constructivist approach informed by grounded theory [45]. In grounded theory method, the theories are constructed by the researcher based on the themes generated from analysing of the data [45].

Ethics

This study was reviewed and approved by the NRES Committees-North of Scotland (Ref: 13/NS/0041) and the research ethics committee of London School of Hygiene and Tropical Medicine (LSHTM) (Ref: 6421). All participants gave written consent to be included to this study.

Sample

Eligible participants were patients aged 18 or over who were fitted with NHS hearing aids at the Royal Surrey County Hospital (RSCH) between January 2011 and January 2012 and reported to use their hearing aids four hours or less per day in response to a screening questionnaire. The screening questionnaire was posted to 1874 patients between October and December 2012 of which 1021 were returned. Invitation to take part in the pilot RCT and the qualitative sub-study was sent to 220 individuals randomly selected (using a computer generated list of random numbers) from 293 respondents who reported that they used their hearing aids for less than four hours a day. Patients who expressed their interest in taking part in the study were offered a session with the author in order to assess them against the exclusion criteria, complete the baseline measures and enrolment to the study. Exclusion criteria were: (1) inability to respond reliably to pure tone audiometry, (2) inability to complete the questionnaires in English language, (3) poor manual dexterity (inability to insert hearing aid to their ear), and (4) presence of medical contraindications for hearing aid intervention as described by the British Academy of Audiology [46].

As described earlier in the pilot study summary, patients who met the inclusion criteria and gave consent to take part (n=37) were randomly assigned to MISC (n=20) or SC (n=17). The random sequence was generated by a statistician prior to commencement of the study and sent to the Audiology office manager for the allocation of participants. The author who conducted the baseline assessment and enrolled the participants had no role in randomisation or allocation of patients.

SC sessions were allocated 60 minutes and involved a hearing aid review appointment with a qualified audiologist with no MI training. Audiologists providing the SC intervention were instructed to manage their patients in the same way as they would do in their routine clinics and no attempt was taken to standardise their activities. Consistent with routine clinical practice, audiologists typically conducted the activities listed below based on the needs of the patient:

1- Discussed patients' problems with regard to their hearing aid use.

2- Checked comfort and suitability of hearing aid and ear moulds/ open tubes.

3- Problem solving, practiced using hearing aid functions, changing batteries, hearing aid maintenance, as well as insertion and removal of the hearing aid.

4- Real Ear Measurements (REM) (if needed, REM had already been undertaken for all patients at the time of the initial fitting as a part of the routine practice).

5- Adjusting the gain-frequency response of the hearing aid(s), feedback manager, acclimatisation setting, compression, directional microphones, loop system and additional programmes as well as automatic applications (when needed).

6- Provided brief education and explanations with regard to (a) patient's hearing status (description of audiogram), (b) why they need a hearing aid, (c) how a hearing aid operates and its limitations, (d) communication strategies/assistive listening devices.

7- Advised the patient that they need to use their hearing aids consistently.

8- Offered them an optional follow up appointment in one week's time.

Patients in the MISC group received MI combined with hearing aid review with the author who is a qualified audiologist with MI training. The MISC sessions were allocated 60 minutes during which the author provided MI combined with the activities related to hearing aid review as described above. Usually the first half of the session was allocated to MI in order to explore and enhance the patient's motivation to use their hearing aids. Instructions and education were provided within the MI component when indicated. The second half was allocated to review and adjustment of the hearing aid settings. The blend of MI with hearing aid adjustment tasks was flexible and based on the needs of each patient. MI was provided based on the principles described by Miller and Rollnick (2012).

Participants were blinded to the group allocation. They were unaware of any specific intervention, other than "we are investigating how to facilitate hearing aid use with two counselling and audiology support approaches. Both approaches seem to be beneficial but we do not know which one is the best. The type of counselling/ audiology support you receive will be selected randomly by a computer." The audiologists who were providing the SC intervention were blinded to the intervention given at the MISC group. Treatment allocation was not concealed from the author after the randomisation.

As there was only a small group of people in the pilot study (n=37), no specific sampling strategy was used and all available participants (n=34/ 37) were interviewed for this sub-study (2 were unable to take part in the in the interview within the study period and one participant deceased).

Interviews

The author interviewed all 34 participants between August and September 2013 at the audiology department, RSCH. The author was known to all participants as he recruited and assessed them as well as providing the intervention for the MISC group. This study was a part of the author's PhD project. The interviews lasted for up to 60 minutes and were audio-recorded. All interviews were transcribed verbatim by an independent transcription agency and provided an account of all verbal and the audible nonverbal (e.g., coughs, cry, pause, laugh, indicating agreement, etc.) utterances.

Interviews were semi-structured and an interview guide was developed in order to prompt the questions (Table 2). The author used a wide range of basic counselling skills (e.g., active listening, reflecting, empathy, non-judgmental, open questions, probing, confronting, etc.) in order to build a good rapport with patients and to make them feel comfortable so they can openly talk about their ideas and concerns.

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Table 2: The guide for qualitative interviews.

This interview can take about 1 hour and will be tape recorded. I like this to be a relaxed conversation so you shouldn't feel under pressure at all. There is no right and wrong answers and I just like to know your opinions. All the interviews will be recorded and transcribed and all personal/ identifiable data will be removed from the transcripts and whatever you tell me will remain confidential. I will summarise the interviews from all participants and write my research paper without mentioning any names or any identifiable information.

I will be asking you questions. Please feel free to answer in any way that you like. You don't have to answer my questions. You can answer them if you like. I would like to hear your honest response. Please do not feel that you have to tell me something that I like to hear. In fact I like to hear how exactly you felt and your opinions. At the end of the interview you will get to ask any questions that you may have and I will do my best to answer all of your concerns.

Tell me about how your hearing aid use was prior to research. What were the positives and what were the obstacles?

How confident were you that you could use your hearing aids if you wanted to?

Tell me your opinion of the review sessions that you have received in this study. What were the good points and not so good points? How these could be improved to suit you better? What is your opinion about the duration and number of visits that you had in this study?

Tell me about the questionnaires that you had to complete. How did you feel about answering to all those questions at home or clinic? How did you feel about recording the hearing aid use via data logging?

From your experience what was the most important thing that you feel that you have gained by taking part in this study? What difference they made in your life and how important they are to you?

How the number of hours that you use a hearing aid could make a difference in your life? Does it really matter to you, whether you use it 4 hours a day or 8 hours a day? Does it make any difference?

Do you have any views about those who don't use their hearing aids or do not come forward for a hearing test? What do you think about those who do?

Data analysis

The method utilised in order to analyse the interview transcripts was based on the six-phase thematic analysis [47]. An inductive approach to thematic analysis informed by grounded theory was adopted and the themes were primarily identified at semantic level [48].

In the first phase, the author read all the interview transcripts several times in full and checked them against the original audio recordings for accuracy. Analytic memos and annotations were taken throughout the process generating a list of ideas about potential codes as well as highlighting segments of the transcripts which were relevant to the research questions. At phase 2, segments of the transcripts relevant to the research questions were coded for potential themes. At phase 3, codes were sorted into potential themes. Codes, themes and extracts of the data are collated together ensuring that the codes and themes are closely representing the data. At phase 4, emergent themes were reviewed and refined. At phase 5, a detailed analysis for each theme was written describing its meaning and its relation with other themes in the data set. In addition, sub-themes were formed for the large and complex themes. Sixth phase included writing up an analytic narrative of the thematic analysis and providing sufficient evidence for the themes within the data (i.e., inserting the relevant data extracts). Themes were not necessarily developed based on the number of the participants identified by them but by their uniqueness and potential influence.

As this was a part of an educational project, the coding was conducted solely by the author; however, the overall process was overseen by the author's academic supervisors. QSR NVivo 10 was used for qualitative data analysis. Consolidated criteria for reporting qualitative research checklist was used to guide reporting of this study (COREQ; 49).

Results

Participants' characteristics

There were 19 males and 15 females. Mean age was 72.2 years (SD=11.5) ranged between 34 and 92 years old. All patients had Oticon Zest NHS Behind-the-Ear hearing aids. As presented in Table 3, there wasn't any considerable difference in the baseline characteristics between the MISC and SC groups.

Table 3: Baseline characteristics or participants in Motivational Interviewing combined with Standard Care (MISC) and Standard Care only (SC).

Characteristics	MISC	sc	
	Mean (SD) N= 19	Mean (SD) N= 15	
Age (years)	75 (8.8)	69 (13.6)	
PTAa of better ear (dB)	31 (10)	30 (10)	
Hearing aid use (hours per day as measured via data logging)	1 (1.4)	1.3 (2)	
International Outcome Inventory-Hearing Aid (range 7-35)	17.6 (6.6)	18.4 (7.5)	
aDTA: pure tana average audiemetric threshold at the frequencies 0.25, 0.5, 1			

aPTA: pure-tone average audiometric threshold at the frequencies 0.25, 0.5, 1, 2, and 4 kHz for the better ear.

Themes and their distributions

Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. Number of themes which were identified in each transcript varied among participants. Most transcripts provided several themes while there were some transcripts Citation: Aazh H (2016) Patients' Experience of Motivational Interviewing for Hearing Aid Use: A Qualitative Study Embedded within a Pilot Randomised Controlled Trial. J Phonet and Audiol 2: 1000110. doi:10.4172/2471-9455.1000110

with a single theme only. The themes comprise: (1) additional support, (2) clinician effect, (3) commitment to research, (4) research process, and (5) feeling better about self. As shown in Figures 1, the theme related to additional support was further divided into 2 sub-themes of (1) hearing aid adjustments, and (2) education, advice and counselling. The theme related to the research process was further divided into 3 sub-themes of (1) motivated by the research process, (2) negative effects, and (3) the effect outside the research team. The additional support and clinician effect seemed to be related to the target interventions provided but the commitment to research, research process, and feeling better about self were related to the general research participation effect. Distribution of the themes in the whole sample is shown in Figure 2 and a comparison in distribution of the themes between the MISC and SC groups is shown in Table 4.



Figure 1: These are themes emerged from the transcripts with regard to the participants' perspectives about the key components of the research programme.



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Table 4: Distribution of themes between MISC and SC groups.

Themes	MISC	SC
Clinician effect (17/34)	9 (53%)	8 (47%)
Additional support (28/34)	-	-
Hearing aid adjustments (17/34)	9 (53%)	8 (47%)
Education, advice and counselling (26/34)	15 (58%)	11 (42%)
Commitment to research (14/34)	10 (71%)	4 (29%)
Research Process (15/34)	-	-
Motivated by the research process (10/34)	5 (50%)	5 (50%)
Effect outside the research team (4/34)	1 (25%)	3 (75%)
Negative effects (5/34)	2 (40%)	3 (60%)
Feeling better about myself (20/34)	12 (60%)	8 (40%)

Theme 1: Clinician effect

Fifty percent of the patients (17/34) described that the most helpful part of the research programme was related to the audiologist's attitude. The theme of clinician effect was not necessarily linked to the specific content of the interventions provided but was rather related to the fact that a caring professional taking interest in them and exhibiting a more supportive attitude which seemed to be missing from their original NHS hearing aid fitting session. Several patients attributed the change in their hearing aid use (increased usage) to the audiologist's attitude. Eight out of nine of the participants in the MISC group and three out of eight of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use.

"[the reason for improvement was] responding to the attitude and support of the staff at Royal Surrey, I include yourself." (P15MISC)

"Well her whole attitude, seemed to be geared to, not only the study but actually helping me to use it as you have done. Only the fact that I could talk to somebody like yourself that understood what the issues were." (P16SC)

Theme 2: Additional support

Eighty two percent (28/34) of participants felt that the research offered them some additional support to the routine care in the NHS.

Several patients pointed out that additional support to their initial NHS fitting session was needed and taking part in the research study provided an opportunity for them to receive such care and support.

"I suspect I wouldn't have had quite the amount of time and attention that you and she have been given as a result of this research." (P15SC)

"I think the main thing [helped him to improve hearing aid use] was the first thing I said, the after sales service which I'm getting now, well, a lot of people need more." (P24MISC) This theme was divided into 2 sub-themes of (1) hearing aid adjustments, and (2) education, advice and counselling. They are described in more details below.

Subtheme 1: Hearing aid adjustments

Fifty percent of participants (17/34) said that adjustment of their hearing aids helped them to use them more often. Eight out of nine of the participants in the MISC group and three out of eight of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use.

"There has been a change along the lines that some of the feedback is certainly less than it was previously, which I found pretty objectionable for things like driving a car or something like that, and I wouldn't wear hearing aids in the car because of that. Now I can wear the hearing aids and it's perfectly acceptable, and I don't really know I've got them in." (P28MISC)

"Yes. Yeah, that, because before it was like a tinny, robot sound all the time. So now it's much better. There's still some distortion at times, but it's much more of a natural voice that I hear. Whereas before it wasn't, it was just robotic." (P11SC)

Subtheme 2: Education, advice and counselling

Seventy six percent of the participants (26/34) felt that the education, advice and counselling contributed to their decision on using their hearing aids. Eleven out of 15 of the participants in the MISC group and four out of 11 of the participants in the SC group who were identified with this theme showed over four hours improvement in their hearing aid use. There wasn't a clear distinction between the elements of this theme. Often people described their experience of receiving "counselling", "advice" or "education" interchangeably or together. For this reason sub-themes were not created for this category.

Several participants described that gaining more information about their hearing impairment and amplification encouraged them to use their hearing aids more consistently. They felt that they were not given enough information at their original NHS fitting session.

"And it is, and then when you said that your brain needs to get used to having it communicating with it, I think that's something I didn't realise before. And the more you use it, the more your brain gets used to it and I'm sure if anybody had said that to me before, I might have taken more notice." (P32MISC)

Some participants described that instructions and advice provided by the audiologist helped them to use their hearing aids more consistently.

"And it's like, she just makes you try and build you, just says you can use it at home first and then the week after use it out and then the week after use it in the car." (P2SC)

Several patients described that the reason that they used their hearing aids was the fact that they were told to do so. However, it is not clear why they haven't complied with the same advice probably given to them at the time of their original NHS hearing aid fitting session. Often probing questions revealed that it was not necessarily the lack of information but the fact that they didn't feel that they needed to use their hearing aids was the main barrier.

Theme 3: Commitment to research

Forty one percent (14/34) of the participants linked the change in their hearing aid use to their commitment to the research programme. They expressed that the main factor which motivated them to change their hearing aid use was their participation in the research. They believed that by accepting the invitation to the research they were in fact made a commitment to use their hearing aids. In the other words, commitment to research seemed to be a key motivation for change in their behaviour of hearing aid use.

"Yeah, well I mean I was part of the research programme so I mean I wanted to give it the best opportunity, so it wasn't, as you say, the technical adjustments at the beginning but I just wanted to give it the best opportunity over the six week period, so, yeah." (P1MISC)

"because I committed to the research programme, I committed to using the hearing aid. Only the fact that I agreed to participate in the programme and it would be pointless my agreeing to participate in the programme if I wasn't going to wear the hearing aid." (P6SC)

Theme 4: Research process

Forty four percent of the participants (15/34) expressed that their interaction with the process of research influenced their decisions about their hearing aid use. This theme was mainly focused on the effects which were not necessarily limited to the interventions delivered by the audiologists. Several participants described that the main effect of the research was related to engaging with the process of research as a whole (e.g., receiving the invitation letter, completing questionnaires, initial assessment, giving consent, and follow up sessions, etc.).

The influence of the research process was not always positive and some patients expressed some negative effects as the result of engaging with the research process. Moreover, the research process effect was not always directly related to the planned components of the research programme and few patients mentioned that they received influences from outside the research team during the study period. The theme of the research process is sub-divided into 3 sub-themes of (1) motivated by the research process, (2) negative effects, and (3) effects outside the research team. These subthemes will be described separately in the section below using the direct quotations from the transcripts to illustrate them.

Subtheme 1: Motivated by the research process

Overall 10/34 believed that engaging with the research process was the main stimulus helping them to change their behaviour. This theme was differentiated from the commitment to research because it didn't imply that they were committed to the research. Instead, they felt motivated to use their hearing aids because of getting involved in the research.

Commitment to research theme represents a conscious decision that because I am committed to the research, I also am committed to use my hearing aids. This is in contrast with the research process which represents a desire to improve one's use of hearing aids because of taking part in the research. In the other words, for those identified with motivated by the research process theme, taking part in the research created a momentum to start using their hearing aids.

For instance, one patient described that receiving the invitation to research letter triggered his motivation to use his hearing aid.

"I think the motivation for me came as soon as the questionnaire arrived [invitation to research accompanied by the Patient Information Leaflet], it started making me think about my hearing then. So I was already motivated.I was always going to do it, yeah." (P33MISC)

Some patients felt that the research process as a whole was the main factor not the individual tasks taken by their audiologist during the intervention sessions.

"I don't know what she [the audiologist] did that made me do that [use my hearing aid consistently], I think it was not herself, but the process, the whole situation." (P10SC)

Subtheme 2: Effect outside the research team

Twelve percent of participants (4/34) described that taking part in the research programme encouraged them to talk about their hearing impairment with their peers, family and friends. This resulted in gaining more support from the people outside the research team.

"I now know that there are people, because I've talked about this hearing aid study to other people and I know there are people at the golf club who wear, because I see them now wearing their hearing aids and it doesn't bother them and it doesn't bother me anymore." (P16SC)

Subtheme 3: Negative effects

The effect of the research process did not always encourage the participants to use their hearing aids. Fifteen percent (5/34) felt that various stages of the research had a negative impact on them. Some patients described that during the process of the research they felt that they were pushed into accepting that they were doing something wrong. The research components that gave them this impression were mainly the information leaflets and the assessment questionnaires.

"That is incredibly difficult, really is difficult, because I have felt some pressure during all these questionnaires, interviews, blah, blah, blah. All of this research of yours, is geared towards, the deaf person is not doing all they could to help themselves, so let's push and nudge and prod, and try and make them, you know, get more, as much out of life as they can, hearing wise, and I don't see it like that."(P3SC)

The negative effects were not always directly related to the components of the research but sometime were related to the reactions of others to the patient's participation to the study. For example one patient said that her children were discouraging her to take part in the research or to use her hearing aids.

"And they're very negative [her children]. They say there's nothing the matter with my hearing. They can't see any reason why I would want to improve it. Well, I'm supposed to go home and say I'm not having it after all. That's what would please them, isn't it? If I go home and say I've changed my mind." (P22MISC)

Theme 5: Feeling better about self

Fifty nine percent of participants (20/34) expressed that taking part in the research was a selfless act that made them feel better about their selves being able to help others. Several participants described that their main motivation to take part in the study was to give something back to the NHS and do something good by getting involved in the research. They also seemed to feel that using their hearing aids consistently during the study period would be of benefit to the research programme hence they did their best to improve their hearing aid use for altruistic reasons. "We've gained a lot from NHS. And from assistance that we've had and it is, it was something we could do in return. Yes dear. Something we could give back. I think that's quite true. We just thought, what on Earth help can we possibly be? But if we could be of help, then great." (P31SC)

Discussions

Summary of the key findings

Five themes emerged from analysing the transcripts about the participant's accounts of the important factors in the research programme which influenced their hearing aid use. These comprise: (1) additional support: participants benefited from the additional support provided during the research, (2) clinician effect: good patient-clinician relationship, (3) feeling better about self: altruistic reasons, (4) research process: effects of various components of research beyond the target interventions, and (5) commitment to research: people felt that by taking part in the research, they were committed to the research programme and to use their hearing aids.

A combination of the themes was identified for each individual. This indicates that there was no single component in the research process that could be identified as the active ingredient.

Most people highlighted a combination of the themes related to the target interventions (i.e., additional support, and clinician effect), and to the themes related to the research participation effect in general (i.e., commitment to research, research process, and feeling better about self).

Clinician effect

There are many studies in the literature suggesting that effective clinician-patient communication and alliance are closely linked with the patient's satisfaction and their adherence to the treatment (50-59). Grenness et al [60] conducted a qualitative research and interviewed 10 hearing impaired individuals in order to assess their expectations from audiologists. The dominant theme among their participants was the clinician effect. According to their patients, without a good clinician-patient relationship all the other tasks were likely to be inefficient or to fail [60].

It is hard to compare how people felt about the patient-clinician relationship between the MISC and the SC group because they only received either one of them. Hence, all patients were comparing their MISC or SC intervention sessions with their original NHS fitting appointment.

Although the theme of the clinician effect was equally prevalent between the MISC and the SC groups, 8 out of 9 of the MISC participants who were identified with this theme achieved over 4 hours improvement in their hearing aid use compared to only 3 out of 8 participants in the SC group.

This between-group difference may be related to the key elements of MI which are partnership, direction, acceptance, compassion, and evocation in the MISC sessions [29]. The similarities and differences in the clinicians' conversation styles between the MISC and SC sessions as measured independently via MITI 3.1.1 are briefly discussed below.

MISC and SC sessions achieved similar ratings with regard to the direction and compassion but their ratings were significantly different in partnership, acceptance, and evocation [34]. Direction measures the

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degree to which the clinicians maintain appropriate focus on a specific target behaviour during the session (e.g., use of hearing aids) [35]. The global rating for direction was 5 (SD=0) in the SC group and 4.95 (SD=0.2) in the MISC group (p=0.4) [34]. The global ratings in MITI 3.1.1 are in the form of Likert scales of 1 to 5 and average of 4 is required for MI competency level [35]. This indicates that in both the MISC and SC sessions the audiologist exerted influence on the sessions and generally did not miss opportunities to direct the patient toward the target behaviour of hearing aid use.

Compassion is to actively promote the other's welfare and give priority to other's needs. The MITI 3.1.1 does not include any measure that can assess compassion. However, it is likely that in both groups the clinicians who delivered the interventions exhibited a more compassionate attitude compared to the usual care. This is consistent with the feedback received from the participants that appreciated the fact that a caring professional taking interest in them and exhibiting a more supportive attitude which seemed to be missing from their original NHS sessions.

Partnership refers to collaboration and power sharing between the therapist and the patient in such a way that a patient's ideas are valued and influence the direction of the session. This is in contrast to a clinician assuming the expert role and prescribing a treatment. The global rating on MITI 3.1.1 for partnership was 1.5 (SD=0.4) in the SC group and 4.6 (SD=0.5) in the MISC group (p<0.001) [34]. The lower scores on partnership which was shown in the SC group indicates that the audiologists did not work towards a mutual understanding with the patient during the sessions and relied upon a one-way communication based on their expert knowledge (e.g., audiologists at SC rushed into offering solutions to the problems expressed by the patients without further exploring the possibilities, patient's strengths, motivation, ideas, feelings, etc) [35]. In contrast, the higher scores as shown in the MISC group suggest that the audiologist was curious about the patient's ideas and did not rely on authority to achieve progress. Expert knowledge was used strategically not before the patient was ready to receive it [35]. According to MI no one is completely unmotivated for change but they may be ambivalent. Ambivalence is a state of uncertainty and people can stay in that state for a long time [61]. In MI it is important to encourage the patient to explore and verbalise their own reasons, need, desire and ability to change, as opposed to lecturing and giving them information and advice about the benefits of the change, or arguing about the negative consequences of not making the change [62].

Acceptance or empathy which is embedded in MI is a key concept developed by Carl Rogers and involves (1) prizing the inherent worth and potential of every human being, (2) understanding another's internal perspective, (3) honouring their autonomy, right and capacity for self-direction, and (4) seeking and acknowledging the person's strengths and efforts [29,63,64]. Global rating for empathy was 1.3 (SD=0.7) in the SC group and 4.3 (SD=0.4) in the MISC group (p<0.001) [34]. Clinicians in the SC group were generally achieved lower scores on empathy which means that they mainly probed for the factual information in order to offer practical solutions rather than focusing on understanding the client's perspective as described above. Although many participants appreciated the fact that the audiologists have asked them more questions and spent more time on offering solutions compared to a typical NHS appointment, these did not necessarily led to improved hearing aid use in majority of the participants in the SC group.

Evocation refers to actively helping the patient to explore and verbalise their own reasons for change and ideas about how change should happen. This is in contrast with educating or persuading the patient to change [29]. Global score for evocation was 1.4 (SD=0.5) in the SC group and 4.5 (SD=0.5) in the MISC group (p<0.001) [34]. This means that in the SC group the audiologists actively provided reasons for change and education about the change without exploring patient's knowledge, efforts and motivations [35]. Audiologists' enthusiasm during the SC sessions must have been greater than what the patients experienced in their original NHS hearing aid fitting sessions, which might have led to high prevalence of the theme related to the clinician effect even in the SC group. However, the improvement in hearing aid use was greater in the MISC sessions in which the audiologist worked proactively to evoke patient's own reasons for change and ideas about how change should happen [35].

To sum up, although this qualitative sub-study shows that there are several factors that contributed to the improved hearing aid use observed in the pilot RCT [34], consistent with other studies [50,60] the clinician effect seemed to be very crucial from patients' perspective. However, the clinician effect was related to greater improvement in the MISC group compared to the SC. Therefore, enhancing the patientclinician relationship in NHS audiology through adopting an approach which is informed by MI in which audiologists actively explore patients' concerns, ideas, and motivations about hearing aid use could be beneficial in improving hearing aid use.

Hearing aid adjustments

Hearing aid adjustment was an important part of the interventions in both the MISC and SC groups. Many people expressed that hearing aid adjustments helped them to use their hearing aids more often and there was a general sense that NHS doesn't offer enough support after the fitting of hearing aids.

The main barriers to the consistent use of hearing aids as reported by patients are often related to poor performance of the hearing aids, poor fit, and discomfort [2,11,16,65]. Therefore, regular adjustment of the hearing aids in order to ensure that they perform well is crucial. Gopinath et al [65] reported that the lack of benefit from the hearing aids, uncomfortable fitting and difficulty in putting them in were the main barriers to hearing aid use. Bertoli et al [11] reported that the strongest factors associated with non-regular use were dissatisfaction with the hearing aid and difficulty to handle it. Hickson et al [16] reported that when hearing aid users were asked why they did not use their hearing aids, almost 25% described that their hearing aids did not help them to hear better, 11% reported that their hearing aids were too noisy, and 11% had difficulty managing their hearing aids. Wong et al [66] reported that improved performance of hearing aids in noisy environments associates with greater satisfaction with hearing aids.

Hearing aid adjustment component of the interventions provided in the MISC and SC groups was potentially very critical because it could have resolved or improved many of the above mentioned problems. However, 35% of the participants (6/17) who have made over 4 hours increase in their hearing aid use and 71% of participants (5/7) who have made between 2 and 4 hours increase in their hearing aid use did not mention the adjustments of the hearing aids as a beneficial factor. Therefore, it seems that although hearing aid adjustments are very important for some patients, it may not predict successful hearing aid use for others.

Education, advice and counselling

Several participants described that in their original NHS hearing aid fitting session they didn't receive much information about their hearing impairment and didn't fully realise the importance of consistent use of their hearing aids. Problems with the lack of information and education for patients is common in healthcare systems in most countries [67]. A meta-analysis found that patient's adherence to treatment was predicted by greater clinician information giving discussions [50]. A more recent meta-analysis showed that nonadherence to treatment is 1.47 times greater among individuals whose physician is poor in building rapport, empathy, and communication [68]. Failure in communication about the disease and treatment options are among the most frequent sources of patient's dissatisfaction [69-71]. A systematic review on patients priorities for the general practice care revealed that "informativeness" was among the most important priorities of patients with regard to their primary healthcare providers (71). Patients expect their clinician telling them all they want to know about their illness and making them feel free to talk about their problems [69]. A recent qualitative study in the field of audiology reported that the patients emphasised the importance of being informed about their hearing and their hearing aids capability [72].

In the current study, a large number of patients believed that gaining more information about their hearing impairment and amplification did encourage them to use their hearing aids more. This highlights the need to improve provision of information to patients during the first hearing aid assessment and fitting sessions in routine NHS audiology clinics. This is consistent with the results of Kelly et al [73] who conducted a mixed methods study in NHS in order to explore older adults experience with their new hearing aids and to identify what they believed would enable them to successfully adjust to wearing them. They found that the primary need prior and after the hearing aid fitting was information. Similar to the results of this study, their participants described that they received little information about the types of hearing aids, process of receiving audiological services, and information to help them adjust wearing them [73].

Although the theme of education, advice, and counselling was equally prevalent between the MISC and the SC groups, 73% (11/15) of the MISC participants who were identified with this theme achieved over 4 hours improvement in their hearing aid use compared to only 36% (4/11) participants in the SC group. This between-group difference may be related to the manner in which information was provided in the MISC group. In MI an approach called elicit-provideelicit (EPE) is used in order to provide information [29]. EPE approach ensures that the information provided is sandwiched between asking patients views, concerns or permission [61]. Eliciting should happen prior to providing information and it means to encourage the patient to think about the information that the therapist is planning to discuss. This way the patient becomes prepared and ready to receive the information which can enhance the likelihood of the change to happen.

Milstein and Weinstein [74] suggested that simply providing information to people about their hearing impairment may not necessarily improve compliance to hearing aid use if they are not ready for this [74]. In the current study, although 44% of the participants who were identified with this theme achieved over 8 hours of hearing aid use, education, advice and counselling theme was also presented in 70% of participants who achieved less than 2 hours change in their hearing aid use. Therefore, not everyone who found the information, advice and counselling useful necessarily improved their hearing aid use.

Themes related to the research participation

Commitment to research was over twice as much prevalent among the patients in the MISC group compared to the SC group. This is consistent with several studies that suggest MI improves adherence to research studies and reduce drop outs [75,76]. In the other words, the commitment to research may be a mediator for change in hearing aid use.

Selflessness or altruistic motivations has been considered as one of the most common reasons that people taking part in a medical research [77-81]. In this study, several participants described that their main motivation to take part in the study was to give something back to the NHS and to do something good by getting involved in the research. This is consistent with a qualitative study conducted by Canvin and Jacoby [82] who found that patients have a sense of moral duty to take part in research. Patients expressed the wish to help others, the wish to do their bit, give something back, help the researcher, and contributing to scientific knowledge as their reasons for participation [82]. McCann et al (83) also reported similar results. They reported that their participants expressed a willingness to help others and to contribute towards furthering the medical knowledge [83].

Commitment to research, research process, and feeling better about self-seem to be related the well-established research participation effect (RPE) [84] which is described as the consequences of research participation as the result of the overall interaction of the participant with the research process not necessarily the target interventions under examination [85]. The implication of this finding is that if this was not a research programme and people simply were invited for a follow up session as a part of their routine NHS care then the true outcome of the interventions provided in both MISC and SC groups could have been different from what we observed here. This is consistent with what has been highlighted by several authors in the past [84,86-89]. It has been suggested that completing self-report questionnaires, reading the research information leaflets, giving consent, being classified as eligible for a study, being observed and receive feedback may provide an opportunity to change regardless of the target therapeutic interventions [84,86-89]. For instance, it has been reported that just asking people how often they ride a bicycle may increase cycling in some [90,91].

RPE can potentially inflate the levels of hearing aid use in both MISC and SC groups. For instance, in the current study due to the RPE some participants might have improved their hearing aid use to an extent beyond which no more improvement could have been made. In the other words, they reached the performance asymptotes or the ceiling effect, which is described as the level that participant's scores cannot exceed a specific value with more information, additional practice, or retests [92,93]. This could have diluted the intervention effect estimates in the RCT.

It is interesting to explore how participants would react to the interventions in the absence of RPE. This way the effectiveness of the MISC intervention compared with the SC in real clinical settings can be assessed. Therefore, future studies should explore the effect of the MISC on people who are not aware of being studied. This has an ethical problem as informed consent will not be sought from the participants. However, waiving the informed consent has successfully been explored by many authors in the field of public health behavioural trails [94-102]. One way of achieving this is through adopting a clustered randomised trial (CRT) design in which hospital sites rather than individual patients are randomised to provide MISC or SC as their routine care. In CRT design, the interventions are naturally applied at the cluster level. Therefore, waiving informed consent in the CRT design should not necessarily be seen as an impediment to ethical approval as long as it is sufficiently justified to proceed without participants' consent [103,104].

Conclusions

Five themes emerged in relation to the participants' perspectives about the key components of the research programme which influenced their hearing aid use. Most people highlighted a combination of the themes related to the target interventions provided (i.e., clinician effect, and additional support) as well as the themes related to the RPE (i.e., commitment to research, research process, and feeling better about self).

Clinical implications

Several improvements can be made in the provision of the audiological services in the NHS for patients who do not use their hearing aids on regular basis. These comprise: (1) enhancing the patient-clinician relationship through adopting MI conversation style in which audiologists actively explore patients' concerns, ideas, and motivations about hearing aid use, (2) spending more time on patient education and improving adherence through provision of information in the MI style, (3) providing additional post-hearing-aid-fitting support and follow up with regard to the adjustments of the hearing aids.

Implications for research

RPE seems to have inflated the levels of hearing aid use in both the MISC and SC groups and needs to be minimised in future full-scale trials on MI for hearing aid use. In order to minimize the RPE, the future studies should explore the effect of MISC on people who are not aware of being studied through adopting a clustered randomised trial design in which hospital sites rather than individual patients are randomised to provide MISC or SC as their routine care.

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