

Designing a placebo device: involving service users in clinical trial design

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Abstract

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Background Service users are increasingly involved in the design of clinical trials and in product and device development. Service user involvement in placebo development is crucial to a credible and acceptable placebo for clinical trials, but such involvement has not yet been reported.

Aims To enhance the design of a future clinical trial of hand splints for thumb-base osteoarthritis (OA), service users were involved in splint selection and design of a placebo splint. This article describes and reflects on this process.

Design Two fora of service users were convened in 2011. Service users who had been prescribed a thumb splint for thumb-base OA were approached about involvement by Occupational Therapy (OT) practitioners.

Content of the fora A total of eight service users took part in the fora. Service users discussed their experience of OA and their own splints and then tried a variety of alternative splints. Through this they identified the active features of splints alongside acceptable and unacceptable design features. Service users focused on wearability and support with or without immobilization. Fora discussed whether a placebo group ('arm') was an acceptable feature of a future trial, and service users developed a potential design for a placebo splint.

Conclusion and discussion This is the first project that to involve service users in placebo design. Service users are increasingly involved in product and device design and are ideally placed to identify features to make a placebo credible yet lacking key active ingredients. The future trial will include research into its acceptability.

Introduction

Clinical trials are central to the production of evidence informing health-care policy and delivery.¹ Considerable advice exists about how best to involve members of the public or service users in health-related research, including clinical trials.^{2–4} A recent literature review highlights four key areas in which the public have been involved in clinical trial design: review of consent procedures and patient information, suggestion of additional trial outcomes, review of data collection procedures and recommendations about follow-up data collection.⁵ Additionally, earlier stages of trial design necessarily involve specification of interventions to be assessed. This is because the ultimate aim of clinical trials is usually to identify which interventions deliver best outcome for patients and to evaluate the safety and cost-effectiveness of interventions under investigation. The specification of interventions is therefore crucial, and guidance from the UK's Medical Research Council stresses the importance of involving stakeholders in the development of complex interventions.⁶ To date, this principle has been applied in the development of interventions in a variety of health areas, with critical influence on trial design.^{7,8}

While evidence of efficacy and safety from clinical trials is a legal precursor to the release of any new drug into the market, such evidence is not required prior to implementation of most non-pharmacological interventions. However, with the rise of evidence-based health care or medicine (EBM),⁹ clinical trials are increasingly promoted as the means to secure evidence to support non-pharmacological interventions. An increasing number of clinical trials explore these, including self-management and exercise packages,^{10,11} physiotherapy,¹² and psychological therapies for pain.¹³ There is also growing interest in subjecting established interventions to scrutiny in clinical trials. This accords with the agenda of EBM, in which evidence from clinical trials is described as 'gold standard', and also with wider imperatives to maximize cost-effectiveness of health care. For health

conditions in which a range of interventions already exist, then identification of interventions to include in trials is an early stage of research design.¹¹

When there is uncertainty about the efficacy of existing interventions and it is possible that unintended factors might affect outcome, then a clinical trial might include a placebo group (or 'arm'). In a placebo group, participants receive an 'inert' placebo rather than an 'active' intervention; a well-known example of a placebo would be a pill containing an inert substance.¹⁴ Inclusion of a placebo group within a trial enables comparison of outcomes in participants receiving an active intervention with outcome in those receiving the placebo. This indicates whether the intervention or other factors confer any effect, and there has been much debate about how to characterize the 'placebo response' and its association with contextual factors.^{15–18} Uncertainty about efficacy and the possibility that factors other than the 'active' intervention may be influencing outcome are important when making a decision about whether a placebo-controlled trial is ethical.¹⁹

In placebo-controlled trials, trial integrity is maintained by ensuring that trial participants do not know whether they received the intervention or placebo until after trial completion: this is known as 'blinding'. While maintaining blinding, participants in placebo-controlled trials should be informed and understand that there is a chance that they might receive a placebo. This maintains the principle of informed consent to research participation. It is therefore critical that any placebo is credible so that participants are not aware that they have received the placebo, and it is important that inclusion of a placebo is acceptable to potential research participants. Even beyond any ethical considerations, placebo-controlled trials are subject of debate, particularly when placebo groups are included in non-pharmacological trials. Some argue that clinical trials including placebo interventions can provide evidence about whether the addition of an intervention has an impact on effectiveness when compared with a basic intervention.²⁰ Others contend that non-

pharmaceutical interventions include characteristic and incidental effects and that this can lead to false-negative results, particularly in trials of complex interventions.²¹

Although a small number of studies report consulting with patients or the public about whether inclusion of a placebo in a trial is acceptable,^{8,22} and examples exist of involving health professionals in placebo design,²² we have found no studies that have actively involved service users in their design. The project described here sought to involve service users in the design of a placebo for inclusion in a trial alongside their involvement in identification of 'active' interventions.

Topic area

Our team is working on a project focusing on osteoarthritis (OA): the leading cause of musculoskeletal pain and disability in adults aged ≥ 50 years. Osteoarthritis affects many joints in the body, but hand OA places particular limitations on daily activity and participation and is associated with pain, reduced strength and stiffness.^{23,24} Estimating the prevalence of hand OA presents challenges because of differences in the nature of information based on presentation of symptoms, self-report or radiographs ('x-ray'). Prevalence in adults assessed by self-report ranges from 4.3 to 6.2%; assessed by radiograph ranges from 20.6 to 82.6%; and assessed through symptoms ranges from 2 to 77.1%.²⁵ Much hand OA is located in the base of the thumb ('thumb-base OA'), with the potential to have more lasting pain, work disability, reduction in quality of life and overall function than OA in other hand sites.^{26,27}

With an ageing population and increased life expectancy, it is important to establish effective interventions for thumb-base OA. Options for OA pain and symptom management include pain relief or anti-inflammatory medication, splints, exercise, topical creams and gels and surgery.²⁸ However, a recent systematic review highlights a lack of high-quality evidence on which to base recommendations for non-phar-

macological therapy of hand OA.^{29,30} In addition, health professionals do not necessarily provide people with hand OA with information or access to the full range of options.³¹

As an option for hand OA, splints aim to provide immobilization, support and pain relief. In the UK, Occupational Therapists (OTs) often provide splints to patients with hand OA, although hand splints are also available on the open market. Splint design has evolved over recent years, with the advent of new materials including thermoplastics, foam and other materials since the 1960s.³² Hand-splint designs now include supportive soft thumb wraps, metal or plastic posts contained within an elasticated fabric, and 'hard' splints made entirely of plastic, individually heat moulded to fit.³³

Hand splints are widely used and readily available, although a systematic review of twelve randomized trials indicated that splints may reduce OA hand pain, but also highlighted that 'the general evidence of the effect of splints and exercise in hand OA is still insufficient'.²⁴ As it is possible that splints may bring about a degree of placebo response in their users,¹⁵⁻¹⁸ and there is a need to understand the mechanisms through which Occupational Therapy (OT) intervention may have effect,³⁴ then a placebo-controlled trial provides the scope to assess these. By including a placebo group in a trial that also evaluates a 'true' splint, exercise and usual care, a placebo-controlled trial can help to provide evidence to inform the provision of care for thumb-base OA, and as yet no studies have included a placebo splint.

Designing a placebo-controlled trial requires particular attention, because a placebo needs to be both credible and acceptable. People who wear splints for thumb-base OA have considerable expertise in acceptable design features, and these experiences can inform the design of a placebo splint. We therefore employed methods of design processes for medical devices that focus on working with users. In particular, we employed principles of participatory design, in which service users and

professionals work together in design decision groups ('fora') to identify key features of a device.^{35,36}

This article describes service user involvement in design of a placebo splint and selection of splints for thumb-base OA. The project will inform a subsequent Delphi exercise and randomized-controlled trial. We present and reflect on the process, acceptability and value of the service user involvement project.

The service user involvement project

We conducted a user involvement project within the development of a protocol for a pilot randomized-controlled trial of splints for thumb-base OA, funded by Arthritis Research UK. The project comprised two forum sessions, which were interactive discussion sessions to identify the acceptability of a variety of designs of hand splints and to design a placebo hand splint for inclusion in the future trial.

The two fora were conducted in 2011: first in Bristol, followed by Keele 10 days later. In Bristol, six women attended the forum, and in Keele, a man and a woman took part. Their age ranged between 56 and 72 years. All forum members had diagnosed thumb-base OA (recent and longstanding, between 9 months and 28 years) and had experience of wearing a hand splint or splints. Potential forum members were approached by OTs working within local hospitals, who identified patients with thumb-base OA and provided them with envelopes containing leaflets about the project, as well as reply slips to return to the University teams should they be interested in coming to a forum. The leaflets provided detail about how the groups would be run, who would be there and why the project was needed. We used an opt-in system, whereby service users were provided with information and were free to decide whether they were interested in coming to the session. We did not record details of anyone who did not contact the University teams. The University teams received eight replies and then contacted potential forum members with

further information about location and practical arrangements. Each forum lasted three hours, including refreshments and breaks. Travel expenses were reimbursed, and group members were each provided with a £40 shopping voucher and helpline telephone numbers. All were offered information from INVOLVE³⁷ about receiving payments. Overall costs for the project included staff time to plan and conduct the fora, vouchers, expenses and refreshments.

The fora were not designed as qualitative focus groups that would generate potentially generalizable new knowledge, and in which service users would be purposively sampled and become 'participants' in research. Instead, they were designed to provide a structure within which researchers and service users could work together to design key elements of the future trial. The project took place under the auspices of existing service user involvement groups at the Universities of Bristol and Keele within which service users are partners in the research process rather than research participants. The distinction between research and service user involvement is described in existing literature and guidance,³ although the difference has implications for whether such activities are seen as generating evidence, which is addressed in the Discussion.

At the start of each session, the project was discussed with forum members, who were asked to sign a form stating that they were willing to 'take part in the forum and to keep confidential the things said today'. They were also asked if they agreed to be audio-recorded, for anonymous quotations to be published, and to future contact.

The fora were designed to be as interactive as possible and were facilitated by two University research staff (RG-H and JA), one of whom is also an OT (JA). Also present were two project Research Fellows at both fora and a Patient and Public Involvement Coordinator in the Keele forum, who assisted with practical arrangements and recording the discussion on audio file, flip charts and notes sheets.

Forum sessions were designed to foster interaction and promote collaboration between staff and forum members and were conversational and discursive. After a discussion of the study and introductions, forum members described their experiences of thumb-base OA and splints. In these discussions, they talked about the things that they could or could not do since having OA, how they obtained their splints, when they wore them and what they thought of them.

In the second part of the sessions, facilitators placed 45 different splints on the table. These splints were all examples of those available within the UK at the time and were new and unworn. Splints were chosen to represent a range of styles and materials (soft, hard, short and long) and were obtained from OTs and splint providers. Forum members tried the splints on and compared them with their own splints. Facilitators worked with the groups and engaged with forum members as they tried splints on. Views about splints were recorded on flip charts, and facilitators established whether views were consensus views or those of individuals. Once forum members had all tried and commented on a range of splints, facilitators described the rationale behind randomized trials and the inclusion of a placebo group. The group discussed their views about the inclusion of a placebo group in a trial of hand splints and optimal OT care. After this, the forum members discussed how a convincing placebo should look and feel. Forum members were encouraged to work with materials that might be used to produce a placebo splint, including thermoplastic and elasticated material.

At the end of the sessions, forum members completed evaluation forms. These asked about levels of satisfaction with the information leaflet, venue, how the team ran the forum, whether their views were taken into account, whether the forum made decisions about the types of hand splints and how to design a placebo splint for use in the final research project. In addition to practical considerations, these questions were designed to identify whether forum members felt that their involvement

would impact on the future trial design, to establish the degree of their involvement. Evaluation forms also included free text sections for forum members to explain their answers and a space for other comments about the forum.

The groups' views

In the first part of each forum session, service users spoke about their experiences of living with thumb-base OA. They described pain and stiffness and loss of strength. Discussion of the everyday experience of thumb-base OA included conversation about how forum members managed, or felt challenged by, everyday activities such as housework, driving, gardening and other tasks requiring dexterity and grip. Some forum members described wearing their splint everyday, while others said they would only wear their splint when pain became 'unbearable' or when engaging in activity that required hand support. Support in painful areas and immobilization were highlighted as useful. Service users' experiences provided context for in-depth discussion about splint design in the second part of forum sessions.

In the second part, facilitators worked with forum members so that they could try on and discuss the wide variety of splints. Building on the previous discussion and comparisons with forum members' own splints, this enabled the identification of acceptable and unacceptable design features. While there was a degree of consensus about these, there was some variation in forum members' views. However, in general terms, the fora identified design features that can be categorized as wearability or on type and degree of support and immobilization.

Factors that affected wearability included warmth, colour, material, method of fastening and washability. Forum members felt that materials such as neoprene could be too hot in the summer. Most people disliked the beige colour of many of the splints, as they felt it was 'too medical' and not a practical colour. However, one forum member did not see this as an issue. Many forum members disliked

hard, moulded plastic splints, and thought that while hook-and-loop fastener ('Velcro'[®], Middlewich-Cheshire, UK) fastenings were easy to put on and off, they caught on clothing. All forum members were concerned about whether splints could be washed. Most were aware of the appearance of splints, and some felt embarrassed that they represented a public declaration of their condition and limitations.

Support and immobilization of the affected joint at the base of the thumb was seen as crucial. If splints failed to provide these, then they were considered ineffective. Some forum members demonstrated how they tightly fastened their splints to provide support and others discussed how they felt benefit if splints applied pressure to painful joints that they might otherwise choose to rub for relief.

Identifying the factors that made hand splints wearable and effective was a crucial step in the process of placebo design. In the next stage of the fora, the materials and design of a placebo splint were discussed. The idea of a placebo group was introduced, with the facilitators using trials of medication to explain randomization and placebo. The presence of current uncertainty about best treatments for thumb-base OA was also addressed. Forum members discussed the idea of a placebo and inclusion of a placebo group within the trial. All thought that these were acceptable ways of achieving information about best treatments for thumb-base OA.

Building on views about the active ingredients of splints, forum members worked on placebo design. The OT (JA) presented two possible options for the hard, moulded plastic elements of a placebo splint that had been developed in collaboration with other OT. Alongside the hard, moulded elements, a range of fabrics that could be used to keep the hard element in place were made available for the forum members to work with. These were discussed, handed round and tried on. Both fora decided that it was crucial that a placebo splint did not offer any 'real' support for the joint at the base of the thumb. To achieve this, one of the hard plastic elements, was better than the

other. The fabrics that the fora worked with were all supportive, elasticated fabrics in beige. Colour was seen as important for a placebo's credibility, although the words used to describe it varied. As one forum member explained: 'the repulsive flesh/pink colour of the splint would be convincing'. The forum members handled the fabrics and worked with the OT to cut them to size in order to fix the hard support in place. This was performed to create the first prototype placebo splint, which forum members tried on. Despite earlier concerns about damage to clothing, forum members thought that hook-and-eye fastenings were appropriate and convincing if they remained secure. In each forum, the prototype was photographed as a record, and all agreed that the placebo design could be based on this idea. Both fora arrived at broadly similar designs, the detail of which will be published alongside future trial findings to maintain trial blinding.

Discussion and development of the placebo provided focus for further discussion of blinding. One forum member pointed out that to retain blinding in the trial, then the study team should ensure that placebo splint wearers should not encounter wearers of active splints, which would be a real possibility at clinics. Forum members all agreed that this was an issue, particularly if those individuals discussed their respective splints and made comparisons about position, level of support and immobilization.

Reflection on process and results of the evaluation

In the fora, the activity of trying splints on engendered discussion about their acceptability and possible effects. The fora did not necessarily seek to build consensus about opinion based on experience, but sought to establish where consensus existed and to debate and discuss individual differences. This then enabled decisions to be made about priorities. For instance in the Bristol forum, one group member felt that splint colour was not important: she was comfortable with beige coloured fabric. On balance, as other group members identified colour

as an issue, it was agreed that colour was as important element of the design of acceptable splints in the future. Furthermore, colour was so salient issue for most group members that all agreed that a credible placebo splint should be beige.

The two fora had radically different numbers of service users present, with six in Bristol and two at Keele. In the group of six, the considerable interaction between forum members was relatively unmediated by the facilitators. In the forum with two service users, forum members asked each other questions, but in the session where they tried on a range of splints, the sessions became more individualized as each forum member had a facilitator working with them on a one-to-one basis. In both sessions, care was taken to scribe the input and decisions of forum members onto flip chart paper. These were fed back and discussed, enabling clarification. In both sessions, all members had the chance to share their experience of OA and splint wear. There were no noticeable differences between the contributions of each group, but additional groups involving more service users might have generated views that were at variance with those recorded here. The groups aimed to serve as platforms for codesign, rather than to provide representative accounts of preferences for splints, with a future trial assessing use and impact of splints in a representative sample of the population.

Forum members completed brief evaluation questionnaires at the end of each session. These elicited information to inform improvements to involvement activities in the future, to assess satisfaction with the decisions made and to ascertain degree of involvement. All forum members were 'very satisfied' that their views had been taken into account, were 'satisfied' or 'very satisfied' that the group had made decisions about splint types to include in a future project and all were 'very satisfied' that the group had made decisions about how to design a placebo splint. Comments about the sessions included: 'very enjoyable, friendly and constructive', 'there was a good range of samples [splints] and it was reasonably easy to choose

the ones we preferred and our views were carefully noted', 'very welcoming and professional and fun!' 'really enjoyable, great to do something positive, lovely to meet the team', 'we were all listened to and I felt really lucky to be involved in it all'.

The next phase of the project is a Delphi study to identify views from clinicians and patients about optimal intervention. Seven of the eight forum members will be involved in the Delphi study. The two fora contribute the following key issues to the Delphi study: splint material and any benefits of hard and soft thumb-base splints, splints issued for different purposes, elements of consultations about splints, contents of optimal consultations and follow-up. Design of the randomized trial will include an 'optimal OT Package' and the placebo group will receive a refined version of the placebo prototype identified in the fora.

Discussion

The fora served to inform the design of a future trial by identifying key features of splints that made them acceptable and by working towards a credible placebo splint. The placebo splint will feature colour, material, fastening and other design features that will make it credible and acceptable. The design of placebo devices raises particular challenges, because a placebo should not contain any of the active ingredients thought provide benefit. Additionally, a placebo should not cause harm. Forum members did not identify any possible harm that the placebo might cause but did point out that to retain blinding the trial design would need to ensure that in clinics, people wearing placebo splints did not encounter those with 'true' splints. Service users' experiences of wearing splints made them ideally positioned to identify features that should be included in a placebo to make it credible and yet inactive.

User involvement fora are becoming widely used as a method of engaging users in health research. Such group-based activities are often described as efficient ways of including the

views and experience of service users within project design and conduct,³⁸ but it is important to evaluate the process. In the hand-splint project, the forum process was acceptable to members, with all expressing satisfaction about how the sessions had led to decisions about the splints and placebo design. Forum members were also satisfied that their views had been taken into account. We assessed these aspects of the fora to identify whether service users felt that their voices and opinions were heard and acted upon. Acting upon these is fundamental to the principle of partnership.

The UK's National Research Ethics Committee Service indicates that many planned clinical trials have no patient or public involvement.³⁹ A recent study found evidence of involvement in only 31% of UK Medical Research Council-supported trials, with most involvement comprising public representation on steering committees.⁴⁰ Although this represents an increase in the proportion of trials with involvement, the role of the public has arguably changed little over the last decade. Ten years ago, public involvement also centred on steering committee or management group membership, development of trial protocols and drafting of information for participants,⁴¹ echoing Boote's more recent findings.⁵

Agreement among professionals that there is 'equipoise' or uncertainty about best treatment is key to the design of ethical trials.⁴² Allied to this, representation of people who represent the trial population in discussions about inclusion of a placebo group has the potential to maximize appropriateness of final trial design. Previous studies have involved stakeholders, including patients, in decisions about whether or not to include placebos in trials. These indicate that the acceptability of placebo inclusion may be condition and treatment-specific. For instance, in Marsden *et al.*⁸ report of qualitative research within the design of a trial about breast cancer treatments, women with breast cancer preferred that a trial of Hormone Replacement Therapy (HRT) would not have a placebo group as they wanted participants to know during the trial if they were taking HRT.

Women also stressed the importance of quality of life as a trial end point, but without a placebo group the authors state that a quality of life analysis would be 'difficult'. Campbell *et al.*²² found that the idea of a placebo-controlled trial of knee surgery was acceptable to members of the UK charity Arthritis Care and to people on waiting lists for surgery. In our hand-splint project, forum members were introduced to the idea of randomization and placebo-controlled trial. All thought that a placebo group was an acceptable option. However, we must acknowledge that we did not discuss in any real detail the available evidence about hand splints, which had led the study team to conclude that a placebo group would be valuable. It is possible that stakeholder involvement even earlier on in the development of the project could have led to more detailed discussion around the need for a placebo. Furthermore, we are aware that the fora were not conducted independently and we could have strived to widen participation. As the forum in Keele only comprised two individuals, this had rather different dynamics compared with Bristol; however, both led to effective involvement as described previously. More generally, broader questions remain about how best to involve service users in decisions about the value and necessity of the inclusion of placebo groups in trials.

In parallel to the growing imperative to involve service users in research design, user groups have been increasingly employed to good effect in product design (including medical devices) within commercial and non-commercial settings spanning medical, industrial and domestic design. Within medical device design and development, the views of service users have provided insight into areas of unmet need, for example in wound care.³⁶ Current pathways for medical device development recommend the involvement of 'end users' from such early stages, through to process of design and refinements of those devices.³⁵ Involvement of service users in placebo design is an example of these principles, and in the project described here, service users were satisfied that they have

contributed to design decisions. Further research is needed into impact of such activity on trial conduct and findings.

We believe that this project represents the first time that service users other than health professionals have been actively involved in the design of placebo devices for a randomized clinical trial, yet their involvement is crucial in making a placebo device acceptable and credible. While it may be that this is taking place, but is unreported, it has been suggested that good quality reporting of public and patient activity is needed to ensure effective evaluation of such work.⁴³ If a clinical trial is considered necessary to generate evidence in a landscape of evidence-based medicine and practice, and if trial participants consent to participation with this knowledge, then researchers have a duty to ensure that any placebo is as appropriate and acceptable as possible.

It is important to note here that the sampling processes used for service user involvement activities, and the methods of analysis, are not intended to lead to research results. This is because the information collected is not subjected to rigorous qualitative analysis processes, and because although approaches to service user involvement often aim to achieve some diversity of experience they do not aim to achieve 'saturation'. Instead, user involvement activities provide practical ways of enabling service user involvement to input into study design, and at the heart of involvement activities is the idea that researchers work 'with' service users rather than conducting research 'on', 'about' or 'for' them.^{3,44} Finding out about service user views about OA and splint wear could have been conducted as a qualitative research project, but the use of product design approaches was itself participatory in nature and places service users as vital partners in the research process, leading onto a future Delphi study. However, it would be fair to say that the participatory nature of the fora is relatively similar to methods of participatory action research⁴⁵ and sought to work in partnership with service users. Participatory research designs are one way to bridge the gap between qualitative research and service user

involvement.⁴⁶ If projects were to use participatory research methods, this would also enable researchers to write up their findings as 'research'. This is important within a context in which findings that are seen as 'evidence' have potential to impact on decisions about policy and services.¹

Forum members thought that the inclusion of a placebo was appropriate and acceptable and were confident that the placebo could be credible. However, forum membership was not intended to represent all patients who use splints, and we do not know how the placebo splint will be viewed when provided to patients in clinics within the future trial. Therefore, it will be important to assess and explore participants' views about the acceptability of the placebo and trial design in a pilot phase of the future trial. This might be achieved through participatory research methods.

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Conflicts of interest

The authors declare that they have no conflicts of interest in relation to this article.

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