

Patient and Public Involvement: Positive Working Examples

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Brief:

- How you have partnered and engaged with patients through your research
- The benefits and challenges of PPI
- Reflections on why you've taken this approach
- Hurdles you have had to overcome

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How:- Effective PPI strategies and output: OTTER Trial

- Stage 1: National PPI Focus Groups
- Stage 2: Establish national PPI database and survey
- Stage 3: Delphi Consensus study with PPI and clinicians
- Stage 4: Pilot Randomised Control Trial

Stage 1: National PPI Focus Groups



Funded
PPI Focus Groups



Stage 1: National PPI Focus Groups



Involving service users in trial design: outcomes, splint selection and placebo design in a trial of treatment for thumb-base osteoarthritis

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Background and aims

Thumb-base osteoarthritis (OA) affects 20% of people aged ≥55. It is associated with long-term pain, work disability, reduced quality of life and overall function.

Optimal management for thumb base OA has the potential to deliver benefits for patients, health services and society. A common approach is splinting. However, previous trials of splints for thumb-base OA have not included placebo groups and it is not clear if they assess outcomes or splints that are important or acceptable to patients.

To address these gaps, and in light of recent evidence about the value of patient involvement in research, we conducted a patient involvement project to inform design of a new trial of splints for thumb-base OA: the OTTER trial.



Findings

1) Outcomes to assess in a future trial

Group members identified impact of OA on everyday and leisure activities. These included: housework, driving, gardening and other tasks requiring dexterity and grip. Splints were mostly used to relieve pain. However, splints hindered some activities and some service users felt embarrassed by them.

2) Identification of acceptable splints

Through discussing their own splints, and by trying other new ones, group members

Methods

Service users: Two involvement sessions took place with a total of eight people (seven women and one man, age 65-72 years) who all wore hand splints for thumb OA.

Session aims: Sessions aimed to identify outcomes to include in a future trial of splints to assess in a Delphi study prior to the trial; and to design a placebo splint.

Session organisation: Sessions were facilitated by a researcher experienced in patient involvement, and a research-lead in occupational therapy. Another research member took notes, and a user support worker attended one session.

Session content: Group members were encouraged to discuss their experience of their use of splints and outcomes of importance to them. They were then shown photographs of various splints, which they discussed and tried. Concepts of randomisation, uncertainty (equipoise) and placebo were introduced. Group members worked alongside the researcher to identify key elements of a placebo splint that would make it convincing and acceptable, and worked on some design possibilities using various materials.

Evaluation: At the end of each session, group members completed brief satisfaction questionnaires.

Evaluation

All 8 service users were 'very satisfied' that their views in the session were taken into account. All were 'very satisfied' that their group had made decisions about the placebo splint. All were either 'satisfied' or 'very satisfied' that their views were taken into account about the placebo design.

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

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This study was funded by Arthritis Research UK, as part of the OTTER trial (ref 1). Further information may be obtained from: Dr Rachael Goberman-Hill, School of Clinical Sciences, University of Bristol, r.g.h@bristol.ac.uk, or Dr Jo Adams, Faculty of Health Sciences, University of Southampton, j.a@southampton.ac.uk

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.

Stage 1: PPI involvement: Case study

Case study: Avril Appleby-Fleming

Avril Appleby-Fleming was one of the patient partners involved in the forum. Avril, now 65, from Devizes in Wiltshire, was diagnosed with thumb base osteoarthritis five years ago. For her it is a serious problem rather than a painful inconvenience, as she earns a living by being an illustrator, and the condition has played havoc with her ability to produce calligraphic hand-writing.

“It’s been very empowering to have been involved in using my own experiences to help inform the clinical trial pilot,” she says. “I’ve found that splints and exercises have helped me very much and I’m much better off than I was.”

- See more at: <http://www.arthritisresearchuk.org/arthritis-information/arthritis-today-magazine/158-autumn-2012/lending-a-helpful-hand.aspx#sthash.UrjwJn7L.dpuf>



Stage 2: Establish national PPI database



Advert placed in Arthritis Today

“Do you have thumb base osteoarthritis and would you like to be involved in helping us design research projects into thumb base OA?”



- 150 + respondents
- National Survey

Patient and public involvement (PPI) in informing the osteoarthritis of the thumb therapy (OTTER) feasibility study: What matters most to people with thumb base osteoarthritis

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Objective

This poster reports on the involvement of our OTTER trial patient partners in identifying what are the most important functions for their daily life, what tasks are the most difficult to perform and what personal strategies are most effective for managing these when living with thumb base OA. Their responses have contributed to the design and development of the OTTER trial outcome measures.

Background

The involvement of public and patient representatives in contributing to the design of clinical research is recognised as good practice. This involvement helps to ensure that what matters most to patients is acknowledged and integrated into clinical effectiveness trial design. The Osteoarthritis Thumb Therapy Trial (OTTER) is a randomised controlled feasibility trial into the clinical and cost effectiveness of an occupational therapy and splint intervention for thumb based osteoarthritis (OA). The OTTER trial is funded by Arthritis Research UK (Trial 19400).

It is known that health care professionals' and patients' views differ when rating functional performance in arthritis (Wylde et al 2006). Additionally, many standardised patient reported hand outcomes do not account for what matters most to patients (Stamm 2009). Therefore from the very start of the design and development of the OTTER trial we sought the opinions of people with thumb base OA to inform us what was most important for patients to be included in the content of patient intervention and outcome measures.

Methods

An advert was published in "Arthritis Today" (Summer 2012) seeking patient partners with thumb base OA to contribute to the design and development of the OTTER trial. One hundred and twenty four people responded to register an interest in joining a national Public and Patient Involvement research data base for people with thumb base OA.

Table 1 What matters most to people with thumb base OA

What is most important to be able to continue to do for patients with thumb base OA?	
Hobbies related to physical exercise	28% (25)
Hobbies related to craft activities	27% (24)
Sedentary activities (reading, watching TV)	20% (18)
Social Roles (Family/grandchildren, teaching/organising)	17% (15)
Music (playing the piano)	9% (8)
What are the most important things to do with your hands for people with thumb base OA?	
Hobbies	34% (24)
Manual activities of daily living	31% (22)
Activities of daily living (washing)	25% (18)
Everything pain free	10% (7)
What are the most difficult hand functional tasks?	
Food preparation	37% (27)
General domestic tasks	21% (15)
Personal/self-care ADL (fastening buttons)	18% (13)
Hobbies and leisure roles (baking/photography)	14% (10)
Social participation roles (shaking hands)	14% (10)
What are the most effective strategies for thumb base pain relief?	
Prescription medicine	34% (26)
Modalities (exercise and massage)	28% (21)
Joint protection	22% (17)
No strategies	7% (5)
Diet	1% (1)
Ignore it	1% (1)

A questionnaire survey was forwarded asking people to identify what was considered to be;

- the most important hand function tasks in daily life
- the most difficult hand functional tasks
- the most effective strategies for thumb base pain relief?

Data were categorized and coded using content analysis by one researcher (KH) and independently checked by another (JA). Key themes were subsequently identified, discussed and agreed independently by both researchers.

Results

There were 51 respondents in total, 9 men and 42 women, aged between 47 and 97 years (mean 70 years) responded. All respondents experienced localized thumb base pain and thumb base OA. Results are displayed in table 1.

Conclusion:

The above results guide the OTTER research team in developing the content of standardised trial intervention and address what matters most to patients. This preliminary work also informs the inclusion of outcome measures that include important sport and craft leisure activities and kitchen and general domestic ADL tasks.

References

- Stamm, T. et al. *Patient perspective of hand osteoarthritis in relation to concepts covered by instruments measuring functioning: a qualitative European multicentre study*. Annals of the Rheumatic Disease, 2009; 68:1453-1460
- Wylde, V. et al. *Personal impact of disability in OA: patient, professional and public values*. Musculoskeletal Care, 2006; 4(3) 152-166

Stage 3: Delphi Consensus study with PPI representatives and therapy clinicians

- National Delphi study of both people with self reported thumb base OA and collaborating clinicians to define and agree trial interventions
- Clinicians and PPI views carried equal weight

Health Sciences   UNIVERSITY OF Southampton

Differences between service providers and users when defining feasible optimal NHS Occupational Therapy treatment for patients with thumb base OA: Results from a Delphi study

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Background

Osteoarthritis (OA) is the leading cause of musculoskeletal pain and disability in middle-aged and older adults. In particular, thumb base OA affects 20% of the population aged 55 years and over [2-5]. The economic burden of OA and with an ageing population and increased life expectancy it is imperative to establish effective interventions. The OTTER (Osteoarthritis Thumb Therapy) trial is a two-year developmental study for a full randomised controlled trial (RCT) into the clinical and cost effectiveness of occupational therapy (OT) and splint intervention for thumb base OA. To develop an optimal package of care for use within a multi-centre RCT, the views of both clinicians and patients are crucial.

Objectives

To conduct a Delphi study to obtain agreement between patients with thumb base OA and allied health professionals (AHPs) concerning the most appropriate optimal NHS programme, splint and placebo splint intervention for use in the RCT. The findings from the consensus study will inform the full trial, and define the three components of the intervention: optimal NHS OT intervention, individualised splint, and the placebo splint.

References

1. Peat G et al. (2001). *Annals of the Rheumatic Diseases*, 60(2), 91-97.
2. Pasle JJ & Pellegrini VD Jr (2000). *Journal of Hand Therapy*, 13, 306-322.
3. Spacko LV et al. (2004). *Osteoarthritis Cartilage*, 12, 366-372.
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5. Sanchez M et al. (2013). *BMC Musculoskeletal Disorders*, 14, 101-107.

This study was funded by Arthritis Research UK, as part of the Further Information may be obtained from: Dr Sofia Barbosa Bouças, Southampton, UK, Email: srb11@oton.ac.uk; or Dr. Southampton, UK, Email: ja@oton.ac.uk. Authors have no conflicts of interest.

Health Sciences   UNIVERSITY OF Southampton

Defining optimal NHS occupational therapy treatment, individualised splint, and placebo splint for patients with thumb base OA: A Delphi study

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Background

Osteoarthritis (OA) is the leading cause of musculoskeletal pain and disability in middle-aged and older adults [2-5]. In particular, thumb base OA affects 20% of the population aged 55 years and over [2-5]. Thumb base OA induces pain and closure of the first thumb web space, which in turn causes an alteration of the pinch grip mechanisms and, therefore, limitation in hand function, and has the potential to have more lasting pain, work disability, reduction in quality of life and overall function than any other hand sites affected by OA [2-5]. Despite the fact that thumb base OA is one of the most common sites of OA and pain, most research on OA focuses on the lower limb. The economic burden of OA is high and with an ageing population and increased life expectancy, it is imperative to establish effective interventions. So far very few treatments have been specifically assessed in thumb base OA. The OTTER (Osteoarthritis Thumb Therapy) trial is a two-year developmental study, for a full randomised controlled trial (RCT) into the clinical and cost effectiveness of an occupational therapy (OT) and splint intervention for thumb base OA. A Delphi study was conducted to obtain a consensus opinion of both patients with thumb base OA and allied health professionals (AHPs) about the most appropriate NHS OT programme, splint and placebo splint intervention for use in the RCT. The findings from the consensus study will inform the full trial, and define the three components of the intervention: optimal NHS OT intervention, individualised splint, and the placebo splint. The Delphi study also sought to determine the experts' opinion regarding the patient reported outcome measures (PROMs) to be included within the trial.

Methods

The Delphi expert panel consisted of 63 AHPs experienced in treating adults with thumb base OA, and 7 patients with thumb base OA. The panel were asked to rate how much they agreed or disagreed about what an optimal NHS OT care for thumb base OA should include; which splint design options should be included in the trial; what should be included in the design of an appropriate placebo splint; and what PROMs to use. The Delphi study comprised 3 rounds. In Round 1, a 38-item questionnaire was used consisting of closed questions and some open questions to allow for additional general and specific comments for the panel's consideration. A seven-point Likert-type scale was used (with items varying from 'Definitely important/likely' and 'Definitely unimportant/unlikely'). The inclusion criteria for Round 1 were as follows: (1) all new factors and issues from Round 1 were included in Round 2; (2) all questions rated 'Definitely/Very important/likely' by 75% or more were excluded from Round 2 but included in the final tool; (3) all questions rated 'Definitely/Very important/likely' by 50-75% were included in Round 2; (4) all questions rated 'Unclear/Unsure' by 50% or more were included in Round 2; and (5) all disagreements between AHPs and patients (i.e., all

In Round 2, a 39-item questionnaire was used consisting only of closed questions. The inclusion criteria for Round 2 were the same as for Round 1 apart from (1) which was excluded. In Round 3, a 19-item questionnaire was used consisting only of closed questions. The inclusion criteria for Round 3 were as follows: for 'users' all questions rated 'Definitely/Very important/likely' by 75% or more were to be included in the final tool; for providers all questions rated 'Definitely/Very important/likely' by 50% or more were to be included in the final tool, everything else was excluded.

Results

The response rate for Round 1 was 49.21% (n=31) for AHPs and 85.71% (n=6) for patients; Round 2 87.10% (n=27) for AHPs and 83.33% (n=5) for patients; and Round 3 96.30% (n=26) for AHPs and 100% (n=5) for patients. Round 3 showed a difference in agreement between AHPs and patients favouring the research team to lower the rate of agreement for providers to 50% or more. The Delphi study provided consensus between AHPs and patients on the optimal NHS treatment for thumb base OA. This included: Education about General OA and Hand OA; Joint Protection General and Hand Specific; Advice on Hand Exercise; Splint Assessment and Provision; Aids and Equipment for Hands;

options were: a short splint distal to wrist; a hard thermoplastic splint; a soft splint; an off the shelf commercial splint; and a therapist manufactured splint. Agreement regarding outcome measurement for thumb base OA included: hand pain, hand mobility; hand function, hand impairment, quality of life, satisfaction, aesthetics, and adherence/non-adherence.

Conclusions

In order to develop a standardised package of NHS care for delivery within a multi-centre AHP RCT, it is imperative to gain the consensus of clinicians and patients about what is important to include in an optimal NHS OT consultation. There are differences in the provision of NHS intervention for people with thumb base OA across the UK. This Delphi study provides clinicians and patient agreement on the optimal components of national OT intervention, splinting and placebo splint design options that reflect optimal NHS intervention and are feasible to provide throughout the UK within national OT departments for use in the OTTER trial RCT.

References

1. Peat G et al. (2001). *Annals of the Rheumatic Diseases*, 60(2), 91-97.
2. Pasle JJ & Pellegrini VD Jr (2000). *Journal of Hand Therapy*, 13, 306-322.

Stage 4: PPI feasibility RCT

- Trial documentation read and reviewed for accessibility, reading and linguistic levels by PPI representatives
- Patient partners wrote trial lay summaries
- Newsletter and summary results posted to all trial participants and PPI representatives
- Named PPI co- applicant on full grant application
- Steering committee membership.

Brief:

- How you have partnered and engaged with patients through your research
- **The benefits and challenges of PPI**
- Reflections on why you've taken this approach
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Benefits

- Outcome measures don't always measure what patients feel is important or valuable to them (Stamm et 2006)
- Realistic, feasible and meaningful intervention components and process for research
- Development of convincing placebo and intervention options

Benefits

- More likely to recruit to target
- Matters to people with arthritis
- More inclusive research team
- **Improves research** “no matter how complicated the research, or how brilliant the researcher, patients/carers and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost effective” (Davies 2009)

Benefits

- Timely - emerging evidence as to effectiveness of PPI (Rose et al, 2011; Hamilton et al, 2011; Gillard et al, 2010)

Challenges- reported

- expectations that patients are not qualified to participate
- views that patients cannot conduct research to a high standard
- patients are not trained as researchers
- patients views are biased
- priorities, motivation and ways of working differ and may cause conflict between patients and researchers
- difficulty to recruit patients who want to be involved in research
- Long term commitment required

(Sweeney et al.2009; Brett et al 2012)

Challenges

- Teams that listen
- Supporting patient partners to contribute in meetings
- Seeking and providing constructive criticism
- Public politics and processes
- Need for experienced PPI mentors
- Recruitment of representative PPI reps

Brief:

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Why?

- It matters personally and professionally
- It ensures research also matters to the people it purports to help
- I don't have arthritis
- It makes sense

Why?

- Effective dissemination
- Better implementation of findings
- Bigger impact
- Essential for FEC funding

Brief:

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Hurdles:

- Engaging (a minority) of clinical researchers
- Lay language from experts
- Finding, encouraging and supporting people from different backgrounds to participate
- Setting up networks of collaborative support
- PPI seeking advice and treatment

PPI integration national level

- PPI checklist developed for all researchers <http://www.sportsarthritisresearchuk.org/seoa/useful-documents-for-researchers.aspx>
- Best practice guidelines for interns and ECRs
- Translation conference events: open inclusive forums



- PPI training, support and mentorship for centre staff, interns and PPI reps in collaboration with RDS, CLARHC

National annual PPI conference

Listen to those
involved in PPI in
what language
they want to be
addressed

Learnt that
INVOLVE provides
excellent
resources for PPI

*PPI is complex but
when conducted
well can be hugely
rewarding*

Language is key to
engagement

Involve PPI reps in
writing lay
summaries

We are
currently not
doing PPI v well

WE DON'T KNOW
WHAT GOOD PPI
INVOLVES

There are wide and
varied learning
needs across PPI
reps and
researchers

Faculty of Health Sciences examples of embedded PPI

Experts by Experience group: Trevor
Kettle

Back care self help group: Dr Lisa
Roberts

Chingford Ladies Epidemiological
group: Dr Cathy Bowen

Independent Cancer Patient Voices
Dr Debbie Fenlon

Multiple Sclerosis Group: Dr Anne
Marie Hughes

HELISK – Lower health literacy
group: Dr Claire Ballinger



Thanks go to...

- All the PPI reps involved in our focus groups, Delphi studies and national surveys
- Cynthia Russell for her work with University of Southampton and South Central RDS
- Vikki Develin PPI/E Officer for Arthritis Research UK CoE Sport, Exercise and OA
- Profs Mark Batt and Nigel Arden- Lead for Arthritis Research UK CoE Sport, Exercise and OA
- Dr Claire Ballinger – PPI Lead Wessex CLARHC
- Ms Ali Bowser – PPI Office South Central Research Design Service
- Heidi Lempp, Denise Pope, Ruth Williams BSR Annual Conference 2014
- Prof David Hunter; Ainslie Cahill, Chris Dickson University of Sydney Arthritis Australia

