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

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

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Abstract

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.”

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
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 (OTTTER) is a randomised controlled feasibility trial into the clinical and cost effectiveness of an occupational therapy and splint intervention for thumb base 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

<table>
<thead>
<tr>
<th>What is most important to be able to continue to do for patients with thumb base OA?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hobbies related to physical exercise</td>
<td>29% (25)</td>
</tr>
<tr>
<td>Hobbies related to craft activities</td>
<td>27% (24)</td>
</tr>
<tr>
<td>Sedentary activities (reading, watching TV)</td>
<td>20% (18)</td>
</tr>
<tr>
<td>Social Roles (Family/grandchildren, teaching/organising)</td>
<td>17% (15)</td>
</tr>
<tr>
<td>Music (playing the piano)</td>
<td>9% (8)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are the most important things to do with your hands for people with thumb base OA?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hobbies</td>
<td>34% (24)</td>
</tr>
<tr>
<td>Manual activities of daily living</td>
<td>31% (22)</td>
</tr>
<tr>
<td>Activities of daily living (washing)</td>
<td>25% (18)</td>
</tr>
<tr>
<td>Everything pain free</td>
<td>10% (7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are the most difficult hand functional tasks?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Food preparation</td>
<td>37% (27)</td>
</tr>
<tr>
<td>General domestic tasks</td>
<td>21% (15)</td>
</tr>
<tr>
<td>Personal/self-care ADL (fastening buttons)</td>
<td>18% (13)</td>
</tr>
<tr>
<td>Hobbies and leisure roles (baking/photography)</td>
<td>14% (10)</td>
</tr>
<tr>
<td>Social participation roles (shaking hands)</td>
<td>14% (10)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are the most effective strategies for thumb base pain relief?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription medicine</td>
<td>34% (26)</td>
</tr>
<tr>
<td>Modalities (exercise and massage)</td>
<td>38% (27)</td>
</tr>
<tr>
<td>Joint protection</td>
<td>32% (17)</td>
</tr>
<tr>
<td>No strategies</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Diet</td>
<td>1% (1)</td>
</tr>
<tr>
<td>Ignore it</td>
<td>1% (1)</td>
</tr>
</tbody>
</table>

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

i. the most important hand functional tasks in daily life

ii. the most difficult hand functional tasks

iii. 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


Wylde, V. et al. Personal impact of disability in OA: patient, professional and public values. Musculoskeletal Care, 2006; 4(3) 152-166

This study was funded by Arthritis Research UK, as part of the OTTER trial (Ref.: 19400). Further information may be obtained from: Kelly Hislop Faculty of Health Sciences, University of Southampton, UK. Email: koho10@soton.ac.uk or Dr Jo Adams, Faculty of Health Sciences, University of Southampton, UK.
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
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, particularly thumb base OA affects 20% of the population 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 TheraPry) trial is a year developmental study for a randomised controlled trial (RCT) into the clinical and cost effectiveness of occupational therapy (OT) and 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 trial interventions: optimal NHS OT intervention, individualised splint, and the placebo splint.

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 Occupational Therapy programme, splint and placebo splint intervention 6 the RCT. The findings from the consensus study will inform the full trial, and define the three components of the trial interventions: 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 RCT.

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 48-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: (i) all new factors and issues from Round 1 were included in Round 2; (ii) all questions rated ‘Definitely important/likely’ by 75% or more were included in the final tool; (iii) all questions rated ‘Definitely important/likely’ by 50-74% were included in Round 2; (iv) all questions rated ‘Uncertain/Unsure’ by 50% or more were included in Round 2; and (v) all disagreements between AHPs and patients (i.e., all options were: a soft 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, mobility, function, hand impairment, quality of life, satisfaction, aesthetics, and adherence.

Conclusions
In order to develop a standardised package of NHS care for delivery within a multi-centre RCT AHPs, 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
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:

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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
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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
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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


- 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
- Involve PPI reps in writing lay summaries
- We are currently not doing PPI very well
- We don’t know what good PPI involves
- Learnt that INVOLVE provides excellent resources for PPI
- PPI is complex but when conducted well can be hugely rewarding
- Language is key to engagement
- 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
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- 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