Clinical physiotherapists had both positive and negative perceptions about delivering two different interventions in a clinical trial: a mixed methods study

Julie Bampton[1], Janine Vargas[1], Roman Wu[2], Stephanie Potts[3], Alice Lance[4], Katharine Scrivener[5], Louise Ada[1] and Catherine M Dean[1,6]

[1]Discipline of Physiotherapy, The University of Sydney, [2]Department of Physiotherapy, St George Hospital, [3]Department of Physiotherapy, Prince of Wales Hospital, [4]Department of Physiotherapy, Blacktown/Mt Druitt Hospital, [5]Department of Physiotherapy, Bankstown Hospital, [6]Department of Health Professions, Macquarie University
Australia

Question: What are clinical physiotherapists' perceptions about delivering two interventions during a randomised trial: the MOBILISE trial? **Design**: Mixed methods study using semi-structured interviews involving closed- and open-ended questions. **Participants**: Thirteen physiotherapists involved in delivering the intervention for the trial. **Results**: All thirteen physiotherapists (100%) had a preference for their patients to get one of the interventions, mostly dependent on the individual patient. Most were frustrated if their patients were not allocated to their preferred intervention but 62% were satisfied with the intervention they delivered and 100% would be happy to be involved in future research. Two significant themes emerged from the open-ended data: that there were both positive and negative aspects of being involved in the trial. The positive aspects included the trial's value as a way of participating in research and as a way of providing evidence for practice. The negative aspects were that the design of the trial was not always reflective of usual clinical practice and the trial's impact on departments, therapists and patients. **Conclusion**: Clinical physiotherapists had both positive and negative perceptions about delivering two different interventions in a clinical trial. However, they were all interested in participating in future research, suggesting that the positive aspects outweighed the negative. **[Bampton J, Vargas J, Wu R, Potts S, Lance A, Scrivener K, Ada L, Dean C (2012) Clinical physiotherapists had both positive and negative perceptions about delivering two different interventions in a clinical trial: a mixed methods study. *Journal of Physiotherapy* 58: 255–260]**

Key words: Therapists, Attitudes, Randomised controlled trial, Qualitative approaches

Introduction

Physiotherapists have a positive attitude to evidence and are interested in using it to improve their daily practice (Jette et al 2003). The move towards evidence-based practice has resulted in an increasing number of randomised clinical trials being carried out. The investigation of interventions that will provide effective and accountable healthcare is only possible when clinical physiotherapists become involved and collaborate in research (Bechtel et al 2006, Stevenson et al 2004).

Most of the literature investigating the attitude of clinicians involved in randomised trials is in the area of recruitment of patients by physicians or nurses (Burnett et al 2001, Embi et al 2008, Somkin et al 2005). On the whole, these studies found that recruitment of patients into clinical trials was low because it was affected by physicians' and nurses' attitudes or beliefs about the value of the research for the specific patient population (such as oncology patients). However, there is one study investigating the perceptions of nurses' and radiation therapists' involvement in clinical trials in a Canadian cancer centre (Sale 2007). These clinicians perceived a variety of ethical and workload concerns associated with clinical trials in cancer.

Most of the focus of clinical trials is on testing the effect of interventions. Therefore, it is not surprising that there has been little or no reporting of physiotherapists' perceptions of their involvement in the research process and whether they perceive their participation to be beneficial to their clinical practice. Clinicians can be involved in a clinical trial in many ways including recruitment, blinded assessments,

What is already known on this topic: Physiotherapists have a positive attitude to evidence to guide their clinical practice, but the involvement of clinical physiotherapists in research is important if clinical interventions are to be investigated adequately.

What this study adds: Clinical physiotherapists who participate in research by delivering the intervention in a trial may enjoy the experience and value the evidence generated by the trial. Negative aspects of participating in research may be minimised if the protocol is feasible for the therapists administering the intervention, aligns well with local clinical practice, and does not disadvantage patients who do not participate in the trial. The positive aspects of participating in research generally outweigh the negative aspects.

intervention, measurements, and administration. We were specifically interested in the reactions of the therapists who delivered the intervention and in discovering how the trial fitted within the workplace. The MOBILISE trial (NCT00167531, Ada et al 2010, Dean et al 2010) investigated a relatively new intervention (treadmill walking with body weight support) compared with usual practice (overground walking) in non-ambulatory patients with sub-acute stroke. It involved six sites and took six years to collect data from 130 patients with stroke. Sites were screened and physiotherapy departments that met the inclusion criteria were invited to participate. Participating departments delivered both the experimental and the control interventions according to the randomisation schedule. External funding provided research assistance for screening, recruitment, and measurement of outcomes. Physiotherapists delivering the interventions received training and ongoing support from the research team during the trial. Therefore, the research question for this study was:

> What are clinical physiotherapists' perceptions about delivering the intervention during a randomised trial?

Given that attitude shapes behaviour (Fishbein and Ajzen 2010), understanding clinicians' perceptions of participating in a randomised trial may provide insight into factors that impact on collaboration with clinicians in future clinical trials and that may help researchers to plan trials that are likely to be acceptable to clinicians.

Method

Design

A mixed methods study was carried out which involved a semi-structured interview comprising both closed-ended and open-ended questions about physiotherapists' perceptions of being involved in a randomised trial. Physiotherapists involved in delivering the intervention in the MOBILISE trial were contacted by email to see if they would be interested in participating in this study. The participating therapists then underwent an interview either face-to-face or via telephone. All interviews were carried out by the same researcher, who had a Masters Degree. This researcher did not deliver the intervention and was not employed by any of the sites that participated in the multicentre MOBILISE trial. Interviews of up to 45 minutes were conducted using an interview guide (Box 1). The first half of the interview consisted of closed-ended questions requiring yes/no answers with participants being invited to explain their responses. The second half of the interview consisted of open-ended questions allowing the participants to elaborate on their experiences of being involved in the trial. Responses were recorded by detailed notes during the interview. The interviews were conducted within six months of the physiotherapists finishing their involvement in the MOBILISE trial. More specific information about the design and intervention of this trial can be found in Ada et al (2007).

Participants

Physiotherapists who had been involved in delivering the intervention in the MOBILISE trial were included if they were qualified physiotherapists, prepared to undergo a semi-structured interview, and had delivered the intervention to at least one control and one experimental patient. They were excluded if they had been involved in carrying out the intervention for less than one year.

Box 1. Semi-structured interview questions

Closed-ended questions

When you were involved in the MOBILISE trial:

- Did you have a preference for your patients to get one intervention or the other? If yes, which one?
- Did your preference vary depending on the individual patient?
- Did you find it frustrating if your patient was not allocated to the intervention you preferred them to get?
- Were you satisfied with the intervention you delivered to your patients?
- Do you have a view on what the results will show? If yes, what is it?
- Are you happy to be involved in another research project?

Open-ended questions

To begin the process of gaining non-directional responses the participants were asked the following question:

- Is there any feedback you would like to give the researchers?

Further open-ended questions were developed from here as the interview progressed.

Data analysis

Answers to the closed-ended questions are presented as number (%) of participants. Answers to the open-ended questions were examined using thematic analysis (Rice and Ezzy 1999). Initially, the text of each interview was read several times to identify concepts which were then coded. The codes were compared and codes expressing related concepts were grouped together to create ***categories*** that linked codes across interviews. These categories were then examined for common clusters of similar issues and organised into ***sub-themes***. Finally, the sub-themes were reinterpreted in light of their categories and brought together to illustrate higher order ***themes*** that encompass the principal ideas in the data (Attride-Stirling 2001). To enhance credibility, the data were analysed independently by two researchers (JB, JV). Subsequent discussion focussed on resolving discrepancies until full agreement. In addition, peer debriefing was used whereby interim analyses were discussed by the group of researchers.

Results

Characteristics of physiotherapists

All physiotherapists who fulfilled the inclusion criteria (n = 13) agreed to participate. They had a mean of 10.2 years (SD 8.8, range 1–30 yr) clinical experience and a mean of 3.4 years (SD 1.8, range 1–7 yr) involvement in the MOBILISE trial. These 13 physiotherapists represent 52% of all the physiotherapists involved in delivering the intervention for the MOBILISE trial and they delivered 77% of the total intervention (66% of the experimental intervention and 89% of the control intervention). Eight (62%) of them had been involved in a research study before. On average, each physiotherapist delivered the experimental intervention to a mean of 3.2 (SD 2.7, range 1–10) patients and the control intervention to a mean of 4.2 (SD 3.6, range 1–10) patients (Table 1).

Table 1. Characteristics of participants

Participant	Clinical experience *(yr)*	Previous involvement in research *(Y/N)*	Involvement in MOBILISE *(yr)*	Intervention delivered to experimental group *(n)*	Intervention delivered to control group *(n)*
1	24	Y	2	3	3
2	10	Y	7	7	5
3	10	N	5	10	9
4	8	Y	4	2	5
5	20	Y	6	5	11
6	5	N	3	2	2
7	3	N	2	4	10
8	7	Y	4	1	3
9	5	N	3	3	1
10	30	Y	3	1	2
11	5	Y	1	1	1
12	1	Y	1	2	2
13	5	N	3	1	1
Mean (SD)	10.2 (8.8)		3.4 (1.8)	3.2 (2.7)	4.2 (3.6)

Table 2. Number (%) of physiotherapists answering 'yes' to the closed-ended questions.

Questions	n = 13
When you were involved in the MOBILISE trial:	
Did you have a preference for your patients to get one intervention or the other?	13 (100)
Was your preference for treadmill walking?	3 (23)
Was your preference for overground walking?	1 (8)
Did your preference vary depending on the individual patient?	9 (69)
Did you find it frustrating if your patient was not allocated to the intervention you preferred them to get?	8 (62)
Were you satisfied with the intervention you delivered to your patients?	8 (62)
Do you have a view on what the results will show?	12 (92)
Is your view that treadmill walking will do better than overground walking	4 (31)
Is your view that overground walking will do better than treadmill walking	1 (8)
Is your view that there will be very little or no difference?	7 (54)
Are you happy to be involved in another research project?	13 (100)

Therapists' perceptions from closed-ended questions

Table 2 summarises the physiotherapists' responses to the closed-ended questions. All 13 physiotherapists (100%) reported they had a preference for which intervention their patients received once they were admitted to the study. Most did not have a blanket preference for one intervention or another; rather it varied depending on the presentation of the individual patient (eg, the level of assistance required to walk). The majority of physiotherapists also reported feeling frustrated if their patient was not in the group that they would have preferred them to be in. Despite this, 8/13 (62%) of physiotherapists reported being satisfied with the intervention that they delivered to their patients during the MOBILISE trial.

Before the results of the MOBILISE study were known, approximately one-third of the physiotherapists thought that the experimental group (treadmill intervention) would do better than the control group (overground walking). A quarter of physiotherapists thought there would be little difference and another quarter thought there would be no difference between the two interventions. Only one (8%) physiotherapist thought that the control group intervention would do better and one (8%) physiotherapist was unsure of the outcome.

All 13 physiotherapists (100%) reported that they would be happy to be involved in research in the future.

Therapists' perceptions from open-ended questions

On analysis of the open-ended questions, two main themes became apparent:

1. Positive aspects of being involved in clinical research
2. Negative aspects of being involved in clinical research

Theme 1: Positive aspects of being involved in clinical research. This theme consists of two main sub-themes: value of the MOBILISE trial as a way of participating in research and also as a way of providing evidence for practice (Table 3).

There were a number of ways in which participation in the MOBILSE trial was perceived by physiotherapists as being of value. First, they felt aspects of the trial design were feasible to carry out and reflective of clinical practice.

> *Good design trial because half hour was very reflective of clinical practice, clinically focused trial.* (P1)

> *Trial didn't affect routine and was okay to participate.* (P9)

Second, they felt the research team offered them good support in carrying out the trial and keeping them informed as to how it was progressing.

> *It was good to have someone independent coming in once a week to keep it on agenda.* (P9)

> *Regular updates on how the trial was going were very beneficial and helped us to stay motivated on such a long trial.* (P6)

Third, some physiotherapists reported that the trial record keeping was not a burden.

> *Paperwork was okay, kept idea of practice.* (P11)

> *Paperwork was not onerous.* (P10)

Fourth, the physiotherapists indicated benefits from using equipment supplied by the research team to deliver the interventions.

> *Specially-designed chair was very helpful in protecting therapist's back.* (P5)

> *Litegait is good harness system for heavy patients.* (P2)

Finally, participants generally enjoyed participating in the trial.

> *Glad to be involved.* (P9)

> *Therapists have enjoyed participating.* (P10)

In addition, many of the physiotherapists expressed that a trial such as this should be helpful in furthering the knowledge base for clinicians delivering rehabilitation to stroke patients.

> *Very valuable trial to get valid evidence to support use of treadmill.* (P8)

> *There is a need for more of these trials for evidence-based practice.* (P9)

Theme 2: Negative aspects of being involved in clinical research. This theme consisted of 2 main sub-themes: that the intervention delivered during the MOBILISE trial was not always reflective of usual practice and that there was some negative impact on departments, therapists and patients (Table 4).

The majority of physiotherapists pointed out the challenges in following the intervention protocol and how it sometimes differed from usual practice in terms of the amount of therapist assistance allowed during walking training.

> *Assistance of 1 person does not represent normal practice, 2–3 assistants are the normal.* (P7)

> *Real clinical practice would have less gait training, 2 assistants and gait training that focused on quality rather than quantity.* (P13)

Second, the protocol differed in terms of use of aids to train walking.

> *Some patients are usually trained with a walking stick, which clashed with the protocol.* (P5)

Table 3. Theme 1: Positive aspects of being involved in clinical research.

Sub-theme	Categories
Value of the MOBILISE Trial as a way of participating in research	Design was feasible to carry out and reflective of clinical practice Research team offered good support Record keeping not burdensome Benefits of equipment being supplied Therapists enjoyed participating
Value of the MOBILISE trial as a way of providing evidence for practice	Results will be valuable evidence for practice

Table 4. Theme 2: Negative aspects of being involved in clinical research.

Sub-theme	Categories
Intervention of the MOBILISE trial not always reflective of usual practice	Amount of assistance restricted Use of aids restricted
Impact of the MOBILISE trial on departments, therapists and patients	Trial patients given priority Intervention is extra burden on physiotherapists Group allocation disadvantages some patients Patient morale affected

Measure for walking without aids was not indicative of how people often go home – using aids is more indicative. (P8)

The issue of how participation in the study affected departments was mentioned. There was a feeling that patients who were enrolled in the MOBILISE trial were prioritised over other patients so that the protocol could be adhered to and that this may affect their discharge date.

Patient's in the trial received more therapy than those not in the trial because of protocol adherence. (P4)

Half an hour on treadmill was too long for therapists as they are required to attend to other patients in the rehab ward. (P7)

In terms of the impact of the trial on physiotherapists, they reported some extra burden.

Treadmill is hard work on the therapist, half an hour in a row. (P4)

Participation in the project did take extra time such as paperwork. (P7)

Some physiotherapists expressed that the patients in one or other group were disadvantaged by the constraints of the protocol.

Treadmill group had limited overground walking practice because they had to reach 0.4m/s first, could be longer time, overground and treadmill are different skills. (P3)

Patients with poor planning need both treadmill and overground. (P4)

There was also a perception that the trial had an effect on patient morale.

Only once a week to try overground walking over 10-m Walk Test was a problem for morale of patients. (P3)

Patients felt like they had to stay on the therapy because it was a study. (P4)

Discussion

The results of this study indicate that physiotherapists involved in delivering the intervention in a randomised trial have both positive and negative perceptions about their involvement in the research process. Despite most of the physiotherapists having a preference for which intervention group they would like each of their patients to be in and being frustrated if their patients were in a different group, the majority were happy with the intervention they delivered. In general, the physiotherapists felt the participation in clinical research was something they could manage and that they were well supported by the research team. Furthermore, the physiotherapists felt they were contributing to the body of evidence for clinical practice. On the negative side, physiotherapists felt that the design of the trial was restrictive by not always being reflective of routine practice and that trial participation sometimes had a negative impact on themselves, the patients, and the department. However, the overriding perception was that of enjoying the trial and a wish to be involved in further clinical research.

There were two aspects of the MOBILISE trial that may have influenced the perceptions of the physiotherapists. First, since this trial compared usual practice with a novel intervention, the physiotherapists had to deliver two different interventions. This meant that, regardless of which intervention they thought was most appropriate for an individual patient, they might have had to deliver the other intervention. In many trials, the control group either receives no intervention or only one intervention is delivered per site in a cluster-randomised trial. Despite all the patients meeting a stringent inclusion criterion (not walking within one month after stroke), physiotherapists had strong opinions about which intervention would suit individual patients. However, they were all prepared to follow the trial protocol in spite of these opinions because of their commitment to gathering evidence that would be relevant to their clinical practice. Second, the design of the trial was such that patients received the intervention until they could walk (or were discharged), ie, there was no defined time of participation in the trial. Physiotherapists commented that this might have had an impact on the decisions made about individual patients, eg, discharge date being changed in order to keep a patient in the trial. However, there is no indication that one group benefited from this more than another.

There is little research exploring perceptions of health professionals delivering the intervention in trials. There is one study investigating the perceptions of nurses and radiation therapists in a Canadian cancer centre where over 50 clinical trials actively recruit patients at any one time (Sale 2007). These clinicians perceived a variety of ethical concerns associated with clinical trials in cancer. Delivering the intervention for patients enrolled in clinical trials was perceived to add to the workload and involvement in the trials was not perceived as a choice. Some of these concerns were similar to and some different from those reported by the physiotherapists in the MOBILISE trial. For example, since all participants in our trial received an active intervention, the concern over delivering a placebo was not relevant. The issue about extra burden was generally not raised as a difficulty by the physiotherapists, perhaps due to the assistance provided by the research team. Similarly, the physiotherapists were volunteers, and this probably accounts for their general positivity. Interestingly, in both trials, the negative concerns were off-set by the commitment to the long-term contribution to evidence.

In future research, the potential for collaboration between researchers and clinicians may be considerable. Physiotherapy is a large profession and this offers advantages to researchers such as access to trial participants. Importantly, this study showed that all the physiotherapists who had been involved in a randomised trial for more than one year were willing to participate in future research. Utilisation of this resource may be optimised if the following factors are considered. The trial design needs to be clinically feasible and relevant. The fact that physiotherapists reported that the trial fitted into their routine indicates that feasible trial designs may be implemented successfully. To participate in a research trial, clinicians need approval from departmental heads. Approval is more likely if a project has direct relevance to the unit. The relationship between the research team and clinicians seems to be important in ensuring compliance and commitment to the trial. The results suggest that investing in this relationship through practical assistance with recruitment, paperwork and answering questions arising during the

course of the trial, may be important to optimise future research. Additionally, providing the trial physiotherapists with adequate equipment may benefit compliance.

This study provides detailed information regarding physiotherapists' perceptions of delivering intervention in a randomised trial. The semi-structured interview method used, including both closed and open questions, ensured comprehensive responses. Key themes emerged from the interviews, suggesting they were successful in exploring physiotherapists' perceptions. A limitation of this study is that not all physiotherapists involved in the randomised controlled trial were interviewed. However those interviewed delivered 77% of the total intervention and a decision was made to include only physiotherapists who had a significant involvement in delivering trial intervention. Since the interviewer belonged to the same profession as the physiotherapists, there is the possibility of biased answers given in the interview (Coar and Sim 2006). However clear negative and positive themes emerged suggesting this was not the case.

Clinicians had both positive and negative perceptions about their involvement in a clinical trial. However, there was a consensus that all of the clinicians were interested in participating in future research, suggesting that the positive experiences outweighed the negative. In the future, evidence-based practice will only be possible if clinicians participate in clinical trials and adhere to the protocols so that an accurate evidence base is built up. A trial that fits into the way physiotherapy departments deliver their service should be more acceptable to both therapists and administrators. The features that make a trial more appealing – such as a clinically feasible and relevant intervention, support from a dedicated research team, and provision of equipment to make the delivery of the intervention efficient – if incorporated in to the design of future trials, may increase clinical commitment to research. ■

Ethics: Approval for this study was granted by the Human Research Ethics Committee of The University of Sydney (08-2002/2916). All participants provided written consent.

Competing interests: Nil

Support: University of Sydney sesquicentenary grant; NHMRC (Australia) project grant (402679).

Acknowledgements: We are grateful to the physiotherapists who delivered the intervention and particularly those who gave up their time to be interviewed.

Correspondence: Associate Professor Louise Ada, Discipline of Physiotherapy, The University of Sydney, P.O Box 170 Lidcombe NSW 1825, Australia. Email: Louise.Ada@sydney.edu.au

References

Ada L, Dean CM, Morris M (2007) Supported treadmill training to establish walking in non-ambultaory patients early after stroke. *BMC Neurology* 7: 29.

Ada L, Dean CM, Morris M, Simpson J, Katrak P (2010) Randomised trial of treadmill walking with body weight support to establish walking in subacute stroke: the MOBILISE trial. *Stroke* 41: 1237–1242.

Attride-Stirling J (2001) Thematic networks: an analytic tool for qualitative research. *Qualitative Research* 3: 385–405.

Bechtel R, Cleland JA, Smith B (2006) Researchers and clinicians: A growing divide or narrowing gap? *Journal of Orthopaedic & Sports Physical Therapy* 36: 451–461.

Burnett CB, Koczwara B, Pixley L, Blumenson LE, Hwang YT, Meropol NJ (2001) Nurses' attitudes toward clinical trials at a comprehensive cancer center. *Oncology Nursing Forum* 28: 1187–1192.

Coar L, Sim J (2006) Interviewing one's peers: methodological issues in a study of health professionals. *Scadinavian Journal of Primary Health Care* 24: 251–256.

Dean CM, Ada L, Bampton J, Morris ME, Katrak P, Potts S (2010) Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more then overground walking: a randomised trial. *Journal of Physiotherapy* 56: 97-103.

Embi PJ, Jain A, Harris CM (2008) Physicians' perceptions of an electronic health record-based clinical trial alert approach to subject recruitment: a survey. *BMC Medical Informatics and Decision Making* 8: 13.

Fishbein M, Azjen I (2010) Predicting and changing behaviour: the reasoned action approach. New York: Psychology Press.

Jette DU, Bacon K, Batty C, Carlson M, Ferland A, Hemingway RD, et al (2003) Evidence-based practice: belief, attitudes, knowledge, and behaviours of physical therapists. *Physical Therapy* 83: 786–805.

Rice PL, Ezzy D (1999) Qualitative research methods: a health focus. Melbourne: Oxford University Press, pp 72–82, 195–198.

Sale JE (2007) What do primary care nurses and radiation therapists in a Canadian cancer centre think about clinical trials? *Journal of Evaluation of Clinical Practice* 13: 186–191.

Somkin CP, Altschuler A, Ackerson L, Geiger AM, Greene SM, Mouchawar J, et al (2005) Organisational barriers to physician participation in cancer clinical trials. *American Journal of Managed Care* 11: 413–421.

Stevenson K, Lewis M, Hay E (2004) Do physiotherapists' attitudes towards evidence-based practice change as a result of an evidence-based educational program? *Journal of Evaluation of Clinical Practice* 10: 207–217.

