User perspectives on the design and setup of lower limb mirror therapy equipment after stroke: a technical report.

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Abstract (237 words)

Objectives: To co-design lower limb mirror therapy (MT) equipment and setup by working directly with stroke survivors and physiotherapists.

Design: Co-design approach through focus groups.

Participants: Twenty-six participants. Sixteen stroke survivors and ten physiotherapists. Data collection and analysis: Data were collected in an iterative process through two sets of focus groups. Firstly, prototype one of the MT equipment was presented to the participants. They were encouraged to use and comment on it. Then, the key requirements for ankle exercise with MT were presented, and participants discussed whether the prototype one was able to deliver these requirements. These findings informed iterations to the device, and a second prototype was produced and discussed in the second set of focus groups. The final prototype was then produced based on the participants' feedback. All focus groups were audio-recorded, followed by verbatim transcriptions and thematic analysis.

Results: Main characteristics required of the lower limb MT device were found to be: the ability to produce MT ankle exercise from an upright sitting posture, an adjustable angle between 5 to 15 degree from the midline to allow clear lower limb reflection during seated exercise, and a lightweight device to enable easy use for stroke survivors.

Conclusion: This work produced an iteratively co-design lower limb MT to be used with stroke survivors.

Contribution of the paper: This study provides user-centred design of lower limb mirror therapy equipment and set up for use in clinical practice and subsequent research.

Keywords: Mirror therapy; lower limb; stroke; rehabilitation; user-centred design.

1

1 Background

Mirror therapy (MT) is a non-invasive rehabilitation intervention that was first used to reduce
phantom pain in people with a limb amputation [1]. Subsequently, MT has been reported to
have benefits for improving upper and lower limb function after stroke [2,3].

5

6 The majority of research has concentrated on the use of MT for upper limb function after 7 stroke [2]. Studies of MT for the upper limb have used comparable equipment, set-up pf 8 equipment and upper limb functional exercises. These similarities ease the translation of MT 9 into clinical practice [2]. However, there are relatively few studies of MT for the lower limb 10 and the equipment and its set-up is more varied [4–9]. Furthermore, many reports provide 11 insufficient detail of MT equipment and its set-up (e.g., mirror dimensions and participant 12 positioning). Therefore, replicating of research studies and translating findings into clinical 13 practice is challenging.

14

15 Although most study reports state that the mirror was placed in a parasagittal plane between 16 the legs the mirror dimensions varied, e.g., 40×70 cm [4,5], 60×90 cm [6,7], and 50×70 cm 17 [8]. The positioning of participants also varied. For example, a half-lying position [5,9], and 18 a sitting position [4,6]. Important features such as placing the mirror to observe a good 19 reflection, and/or obscuring the sight of the more paretic lower limb are described 20 infrequently. Moreover, there is little, if any, evidence that the users of MT have been 21 engaged in the development of the evaluated equipment despite considerations that user-22 centred design is crucial to the uptake and use of such technology [10–12]. These limitations 23 hamper the use of evidenced-based lower limb MT by stroke survivors and clinicians.

24

25 The purpose of the developmental work presented here is to co-design lower limb MT

26 equipment and its set-up through working directly and iteratively with stroke survivors and 27 clinical physiotherapists.

28

43

Methods 29

30 Design

31 A co-design approach employing two sets of focus groups to understand the users' needs and 32 to engage them closely in the iterative development of the lower limb MT equipment and its 33 setup. This approach enabled: user exploration of the idea; consideration of prototypes; and 34 capturing user-identified design benefits and challenges for production of an acceptable and 35 user-friendly final version [13]. This approach adheres to the central need for meaningful 36 partnerships with key stakeholders to develop innovative technologies [14]. Here the key 37 stakeholders were stroke survivors, and clinical physiotherapists with experience in stroke. In 38 addition, we were guided by the GRIPP checklist [15]. 39 Participant characteristics, recruitment and setting 40 The inclusion criteria for stroke survivors were: 41 aged 18 years or more; • 42 • expressed willingness to participate in the research.

- The inclusion criteria for physiotherapists were:
- 44 qualified physiotherapist registered with the Health Professions Council; •
- experience in stroke rehabilitation. 45

46 Overall, twenty-six people participated in the study:10 physiotherapist and 16 stroke

47 survivors. The age of stroke survivors ranged from 30-70 years. They were all more than six

48 months after stroke onset and were living independently in the community. All participants

49 provided informed written consent before recruitment.

51	Stroke survivors were recruited from local stroke support groups. The first contact was made
52	through emailing gatekeepers of the support groups to inform them about the study and
53	provide them with the ethically-approved participant information sheet (PIS). The
54	Researcher also asked if she could visit the support group to tell its members about the study.
55	On receipt of an invitation from a gatekeeper, the Researcher attended a support group
56	meeting to explain about the study. Those support group members who were interested in
57	taking part were provided with a PIS and had any questions answered. Stroke survivors who
58	provided informed consent were recruited as participants in this study.
59	
60	The subsequent focus groups were held in the support groups to which participants belonged.
61	We aimed to include the same participants in both focus groups but recruited additional
62	participants to replace any people who withdrew.
63	
64	For clinical physiotherapists, the Researcher first contacted the gatekeepers of local stroke
64 65	For clinical physiotherapists, the Researcher first contacted the gatekeepers of local stroke services. The introductory email explained about the study and provided the ethically-
65	services. The introductory email explained about the study and provided the ethically-
65 66	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups
65 66 67	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups
65 66 67 68	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups with clinical physiotherapists during their break time.
65 66 67 68 69	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups with clinical physiotherapists during their break time. Procedure and data collection
65 66 67 68 69 70	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups with clinical physiotherapists during their break time. Procedure and data collection Ankle exercise was chosen as the focus for lower limb MT as it is an advocated component
 65 66 67 68 69 70 71 	services. The introductory email explained about the study and provided the ethically- approved PIS. If the gatekeeper agreed, then the Researcher conducted the focus groups with clinical physiotherapists during their break time. Procedure and data collection Ankle exercise was chosen as the focus for lower limb MT as it is an advocated component of therapy to improve sit-to-stand ability and walking endurance [16]. Before focus groups

75	• ensure that the more paretic foot and lower leg are unable to be seen by the stroke
76	survivor;
77	• ensure that dorsiflexion and plantarflexion could be produced through their full
78	anatomical range;
79	• ensure upright and symmetrical comfortable sitting posture that allows a 90 degrees angle
80	at the hips, knees, and ankles;
81	• mirror therapy equipment needs to be light enough for stroke survivors to set it up/down
82	easily, portable, storable in peoples' homes when not in use, and sufficiently robust so
83	that the possibility of breakage is minimised.
84	
85	The research team then tried out a popular device that is commercially available. The major
86	challenges using this device were: participants were unable to see the reflection of the
87	moving foot while sitting upright and it was difficult to keep the mirror in place whilst
88	allowing a clear reflection of the moving foot. Consequently, it was decided there was a need
89	to develop MT equipment and its set-up.
90	
91	The requirements for lower limb MT, set out above, were used to produce the first prototype.
92	This was then demonstrated to the first set of focus groups. Participants were encouraged to
93	use Prototype One and provide feedback for improving the device with specific attention paid
94	to meet the key requirements. Feedback from the focus groups was used to produce the
95	second prototype, and the process was repeated with the second set of focus groups. This
96	feedback was used to inform the production of the final device. Data collection ceased in
97	each set of participants when data saturation was reached, i.e., no new information was

98 generated, and there were no changes to the identified themes [17].

99	Data analysis		
100	The focus group audio recordings were transcribed by the Researcher on the same day they		
101	were made. These transcriptions were examined using deductive thematic analysis [18] where		
102	the codes were predefined to the meet the study aims, determined by research team		
103	discussion. These pre-defined codes were:		
104	• mirror size		
105	• reflection of the less paretic foot.		
106	• the base of the mirror		
107	• the foot support		
108	• how to hide the more paretic side so user cannot see it.		
109	• sitting posture		
110	• storage and portability		
111	• safety features.		
112	Data were coded using NVivo (NVivo 12 Pro). A second member of the research team read		
113	the transcripts and checked agreement or otherwise with the researcher's analysis [19]. In		
114	addition, transcripts were re-checked for any emergent themes not aligned to the pre-defined		
115	codes, that could contribute to device design. It was planned for any disagreement to be		
116	discussed and referred to a third party, but no major disagreement occurred between the		
117	researchers. Findings were then discussed with the whole research team and fed iteratively		
118	into modifications to the design in producing the final (prototype-two) device.		
11911	19		
120	Results		
121	Participants		
122	Prototype One was considered by 14 stroke survivors (four focus groups) and ten		

123 physiotherapists (one focus group). Prototype Two was considered by nine stroke survivors

- 124 (two focus groups) and five physiotherapists (one focus group). It was planned that the two
- 125 prototypes would be considered by the same participants, but seven stroke survivors and five
- 126 physiotherapists were unable to attend. Therefore, two additional stroke survivors were
- 127 recruited to consider Prototype Two (Fig 1).
- 128
- 129 Prototype One characteristics (Fig 2):
- 130 The specific characteristics were:
- mirror dimensions 90×60 cm;
- Mirror mounting board dimensions 100×70 cm;
- square corners to the mirror mounting board;
- mirror separated from the base;
- mirror angle and the foot support adjustable using screws.
- 136
- 137 Changes to the design required for Prototype Two
- 138 Eight design aspects emerged from participants' consideration of Prototype One (Table 1).
- 139 Prototype Two is illustrated in Fig 2. The main changes were:
- 140 adjustable angle of the mirror to the base between 5 and 15 degrees to allow clear
- 141 reflection of the less paretic foot;
- 142 people undertaking MT to be seated in a regular dining chair for back support to allow an
- 143 upright posture and minimize fatigue;
- adjustable position of the foot support using a system of pins and holes to allow easy
- adjustment according to the leg lengths of individuals;
- ¹⁴⁶ round corners to the mirror and its mounting board to minimise injury potential;
- 147 mirror dimensions reduced to 60×40 cm.

¹⁴⁸ base and mirror mounting board made with a plastic material, to enable easy cleaning.

149

- 150 Changes to the design required for final MT equipment and setup
- 151 Participants identified four aspects of the design of Prototype Two that needed improvement
- 152 (Table 2). The three key changes needed were:
- the equipment needed to be smaller so that it can be carried around and stored in the
 home;
- ,
- 155 the equipment needed to be lighter so that it can be carried using one hand only.
- 156 the angle of the mirror to the base needs to be limited between 5 and 15 degrees because
- 157 outside of this range there is a distorted image of the shank and foot.

158

- 159 Main characteristics of the final MT equipment and setup
- 160 The final MT equipment and setup is illustrated in Fig 2. Essentially:
- 161 users can sit in an upright posture on a regular dining chair with back support whilst
- seeing a good reflection of their less paretic foot;
- the more paretic lower limb is covered by white fabric attached to the back of the mirror
 mounting board;
- 165 the mirror is made from good quality plastic with rounded corners;
- 166 the mirror dimensions are 51×37 cm.
- 167 the dimension of the mirror mounting board is reduced to 15 x 7.5 cm;
- 168 the mirror mounting board is connected to the baseboard with a hinge so that it can be
- 169 folded flat and has a 14 cm wide handle for carrying;
- 170 the mirror-to-base angle is adjustable in positions of 5, 10 and 15 degrees from the
- 171 vertical using an adjustable frame attached to the back of the mirror mounting board;

172 • the foot support is adjustable with a pin and holes system providing five different

173 positions for different leg lengths;

the dimensions of the base are 43 ×35 cm, and 43×17cm when folded to allow ease for
storage.

176 • The MT equipment weighs two kilograms.

177

178 Discussion

This study has produced the lower limb MT equipment and set-up for use in stroke survivors'
homes to deliver ankle exercise. To our knowledge, this is the first co-designed, with stroke
survivors and physiotherapists, MT equipment and set-up for lower limb rehabilitation after
stroke.

183

There were a few studies available to assist us with the initial design of the mirror and its setup [20]. but, these used a mirror twice the size of our final product [4,6,9]. Although the larger mirror should ensure obscuration of the more paretic limb, the stroke survivors in this study preferred using a sheet to cover the more paretic lower limb as this reduced the weight of the equipment.

189

Most of the stroke survivors preferred to use the mirror in the midline between their lower limbs as used in an earlier investigation [2]. However, they preferred to perform the ankle exercise MT in an upright sitting posture using a standard dining-type chair and preferred to adjust the equipment rather than bending their back or tilting their head to see the reflection. Interestingly, other investigations do not appear to have considered participants' posture and how sustainable this is over the exercise period. For example, participants are reported as being in half-lying or a sitting position involving trunk flexion [9] with the trunk inclined

197	towards the less paretic side to allow the view of the reflection of the lower leg in the mirro			
198	[21]. In respect of the mirror angle, a few study reports have mentioned it, for example, an			
199	angle of between 75 and 85 degrees [22,23]. However, participants in this study highlighted			
200	the importance of the angle to avoid shifting the body to see the reflection. They			
201	recommended that the mirror angle needed to be limited between 5 and 15 degrees from			
2022 0 2	vertical to prevent distortion of the images.			
2032 0 3				
204	The main strength of this study was the use of an iterative process to incorporate the views of			
205	stroke survivors and clinical physiotherapists for improving the design of lower limb MT			
206	equipment and its set-up. The strength of this approach could have been improved with the			
207	use of multidisciplinary team meetings, including the participants and the workshop			
2082 0 8	technicians. This was precluded by the resources available.			
2092 0 9				
210	In conclusion, the results of this study provide information to clinical physiotherapists who			
211	are already using lower limb MT with stroke survivors. And, the lower limb MT equipment			

and set-up produced through this study can now be tested for clinical efficacy in subsequent

2132 research.

215 Ethical approval

- 216 Ethical approval for the study was granted by the Research Ethics Committee of X,
- 217 University of X (Ref. 2017/18 117). All participants provided informed consent before
- 2182 they were recruited as participants in this study.
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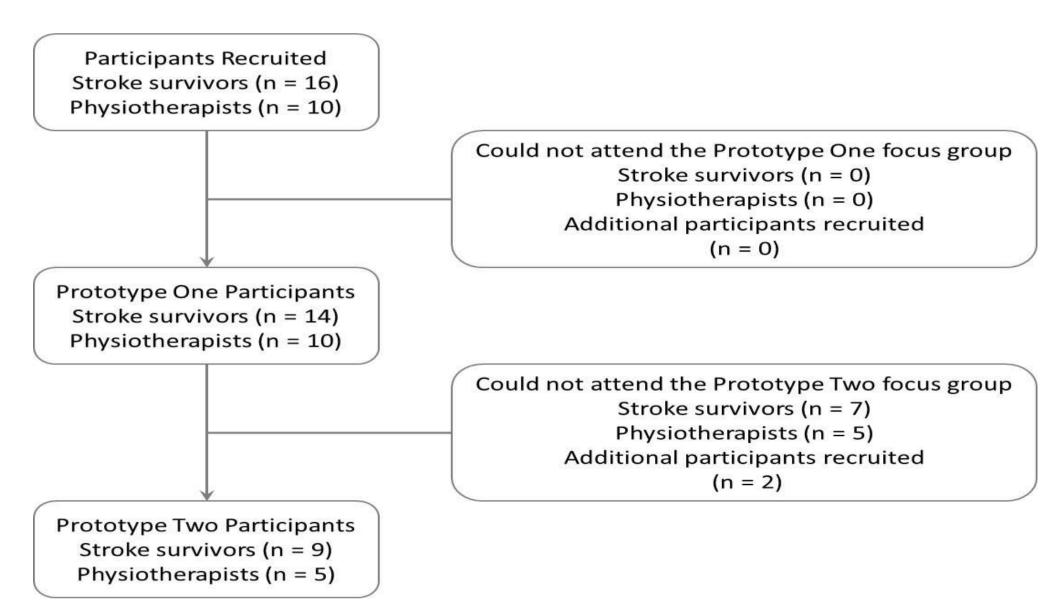




Figure 1. Flow of participants through the study

Figure 2. Prototype One, Prototype Two and final mirror therapy equipment and setup

A. Prototype One: The mMirror was supported by screws at the base to adjust the angle. Also the ankle supporter was attached to the base with screws and, the mounting board was bigger than the mirror size with a sheet attached at the back to cover the weak side.
B. Prototype Two: Changes in the size of the mirror and the base, the ankle supporter was adjustable withwith a pin and holes system andand the corners of the mirror were rounded.
C. Final mirror therapy equipment and setup: An oOverview of the mirror with rounded corners, with handle at the top, the foot is rested on the ankle supporter with the sheet covering the weaker side. An adjustable frame at the back of the mirror with three slots at the base allows the angle of the mirror to be set at 5, 10 or 15 degrees.