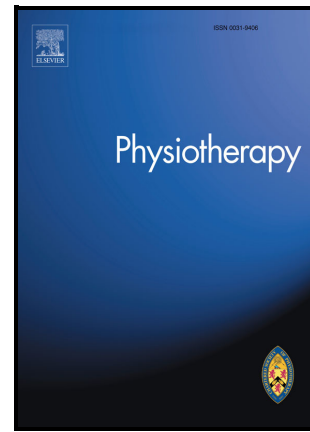


Acceptability of Lycra arm sleeve in people with sub-acute stroke: patients', carers' and clinicians' perspectives

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Acceptability of Lycra arm sleeve in people with **sub-acute** stroke: patients', carers' and clinicians' perspectives

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Ethical Approval

The study received ethical approval from the Southwest - Frenchay Research Ethics Committee (REC reference: 17/SW/01/73)

Suppliers

- a. Jobskin Limited UK, Unit 13a Harrington Mill, Leopold St, Long Eaton, Nottingham NG10 4QG, UK
- b. IBM UK, Business Analytics - SPSS, 2 New Square (B32S), Bedfont Lakes, Feltham, Middlesex TW14 8HB, UK

Contribution of the Paper

- Lycra arm sleeve is comfortable and acceptable by people with acute stroke
- Training the staff, patients, family members is easy and feasible
- Clinical and cost effectiveness need to be tested in future studies.

Abstract:

Background: Previous studies found that the Lycra sleeve has potential to reduce glenohumeral subluxation in people with stroke. The primary aim of this study was to explore the acceptability of the Lycra sleeve from patients', carers' and staff **perceptive in the sub-acute phase of stroke.**

Method: Stroke survivors over 18 years with hemiplegia and muscle strength of ≤ 3 (**Medical Research Council scale**) shoulder abduction, able to provide informed consent **were recruited as soon as they were medically stable.** Patients wore the

Lycra sleeve for up to 10 hours/day for three months. A questionnaire was administered three months post-sleeve application to **immediate and delayed groups and healthcare staff.**

Results: Twenty-seven patients (immediate group (n=19), delayed group (n=8)), 23 carers/family-members and 36 healthcare staff (nurses (n=10), nursing assistants (n=5), physiotherapists (n=10), physiotherapy assistants (n=3) and occupational therapists (n=8) completed a questionnaire. Several staff reported for more than one patient resulting in up to 37 responses to some questions from nursing staff and 46 responses from therapy staff. Of 27 patients, all found the sleeve to be comfortable. The average time to apply the sleeve was between two and five minutes. The sleeve was reported as acceptable in daily life by patients (**96%, n=24/25**), carers/family-members (**96%, n=21/22**), by nurses (**92%, n=34/37**) and in routine clinical practice by therapists (**91%, n=41/45**).

Conclusion: Wearing of Lycra sleeve was acceptable for patients during activities of daily living/rehabilitation. However, research is required on the effectiveness of the sleeve before this can be routinely used in clinical practice.

Key words:

Sub-acute stroke, the Lycra sleeve, Acceptability, glenohumeral subluxation, upper limb function

Background

Glenohumeral subluxation (GHS) is a common post-stroke complication reported in up to 81% of patients depending on the measurement methods used and the time frames over which it is assessed [1-2]. GHS appears to be caused by a lack of

adequate muscular support of the shoulder due to loss of motor control and the reduced force coupling (provided by rotator cuff muscles) to align the head of the humerus in the glenoid cavity, while the patient is in the upright position [3-6]. There is a concern that without treatment, GHS can progress to an uncorrectable degree over time, leaving the patient with reduced shoulder movement [7]. Furthermore, GHS has been associated with hemiplegic shoulder pain, and together these complications can have a significant impact on the recovery of upper limb function [8].

Consequently, management of GHS in the therapeutic setting is considered important and varied approaches have been proposed, both for its prevention and management. These include positioning the arm using lap boards and arm troughs, slings, active exercises, and functional electrical stimulation (FES) [9-13]. Overall, evidence to support the effectiveness of current approaches for management of GHS is limited [14]. Of all the available interventions, there is evidence to support the short-term benefits of FES in clinical practice both for prevention and reduction of GHS and to enhance motor function [15]. Unfortunately, due to time, availability of apparatus, and cost-constraints, use of FES is not common in routine clinical practice; in addition, some people find FES uncomfortable.

To improve clinical outcomes for patients with GHS, other cost-effective and user-friendly interventions are required, and Lycra garments have been suggested as a potential candidate. **Lycra garments are lightweight and flexible and compared to rigid orthoses, they are better tolerated, do not restrict movement or encourage disuse [16]. The garment provides a compressive and supportive**

effect and is considered to influence the neuromuscular activity in the affected body segment [17]. It has been suggested that the garment may enhance sensory feedback and proprioception, potentially through enhancement of multi-segmental, large-fibre, cutaneous input from the skin to the central nervous system [18]. There is strong evidence for functional interplay between somatosensory and motor systems in post-stroke rehabilitation [19]. In addition, it has been postulated that the compression effect of the sleeve may reduce oedema and the weight of the upper limb, therefore decreasing the vertical force on the shoulder [20]. This may reduce subluxation and possibly pain. However, there are very limited studies and effectiveness for preventing GHS and improving arm function after stroke remains to be determined [21].

Recently we conducted a study to assess the clinical effects of Lycra sleeves in reducing subluxation in five people with chronic stroke over a one-week period [22]. GHS (Acromion-greater tuberosity (AGT) distance measurements) was measured using ultrasound before and after application of the sleeve for one week and showed a mean reduction of 0.27 cm (95% Confidence Interval (CI), 0.13–0.40 cm). A larger study on patients with stroke (n=105) reported a cut-off point of ≥ 0.2 cm was considered optimal for ruling-in or ruling-out GHS in people with stroke [23]. Patients' perceptions (using a standard questionnaire) of using the sleeve were positive; they were more aware of the affected limb and able to use their arms more in activities of daily living (n=4).

Before the Lycra sleeve can be tested for its clinical effectiveness in people with stroke, it is critical to test its acceptability in clinical practice. **The primary aim of this study was to explore patients', carers' and staff perceptions, regarding**

acceptability of the use of Lycra sleeves over a three-month period in the sub-acute phase (7 days to 6 months) [24] of stroke.

Methods:

A prospective cohort study design was used and ethical approval was received from XXXX XXXXX XXXXXXXX. XX Participants were recruited from a single NHS Trust stroke service in the xxxxxx xxxx xxxxx xxxxx. Eligibility criteria were as follows: people with stroke aged over 18 years resulting in unilateral weakness, shoulder muscle strength ≤ 3 on Medical Research Council (MRC) scale [25], medically stable and able to provide informed written consent. Patients who lacked mental capacity to give informed consent, or had other neurological conditions, long standing shoulder pathology, or recent neck, arm or shoulder surgery were excluded.

Participants **were recruited from the stroke unit as soon as they were medically stable and followed up in the community after discharge.** Recruitment was conducted between December 2017 and December 2018, with final follow-up assessments completed by June 2019. Each patient gave informed written consent to take part. For those with communication disorders, aphasia friendly information was used and professional help was sought from speech and language therapists, if required. **In addition, family members/carers and healthcare staff (nurses, physiotherapists, occupational therapists, nurse assistants, and therapy assistants)** involved with the patient care were approached and recruited for completion of a questionnaire at the end of the intervention period.

Acceptability of the sleeve was assessed using a questionnaire. Questionnaires for patients, family members/carers **and healthcare staff** were developed based on a previously validated questionnaire used in clinical effectiveness research [20] and co-designed with patient partners. There were common questions for all groups and some specifically targeted at patients and **healthcare staff**. The key features were 1) time taken to apply, 2) adverse effects, 3) acceptability / ease of use, 4) therapy specific implications (patients and therapist), and 5) training related issues (staff and carers). Participants responded on a seven-point Likert Scale. There were free-text boxes following some of the questions to allow elaboration (Appendix 1).

Procedure

Baseline demographic data including age and gender, date of onset, type of stroke, site of stroke, and side affected, hand dominance, use of other orthosis, were collected from patients' medical records by the **research physiotherapist (RJ)**. **In the context of a future comparative study, we were interested to know if there was a difference in clinical outcomes between patients with and without the Lycra sleeve and if patients had any issues waiting to be offered a sleeve.** Therefore, we randomly allocated them into either an immediate group or a delayed group. We chose three months intervention period and this naturally fitted with the practicality of delivering the study according to previously published stroke rehabilitation studies [26]. **Patients in the delayed group who required extended length of stay were still inpatients, while others were seen in their own homes or residential homes three months after recruitment into the study.**

Participants in the immediate and delayed groups received a sleeve immediately and at the three months respectively. Participants in both groups were advised to wear the sleeve for 8-10 hrs/day for three months from the start of the intervention. They were asked to record, on a log-sheet, the time when the sleeve was put on and taken off each day. Throughout the study, all patients received routine care at the hospital and in their own home as part of usual NHS stroke pathway care, including inpatient and Early Supported Discharge team.

Both researchers received training from the manufacturer on the application of the sleeve and **subsequently trained staff, carers and family members**. According to the manufacturers' recommendations, the wrist circumference was measured for each participant and the correct size of sleeve (from three options) was provided. The sleeve was applied from the wrist crease up to the insertion of deltoid on the humerus using the orange applicator (Figure 1). During the application, an external rotational torque was applied while pulling up the sleeve.

Finally, both groups completed a questionnaire on the acceptability of the sleeve at the end of their 3-month period of wearing the sleeve. Assistance was given by **the research physiotherapist (RJ)** in completing the form when needed. **Family members/carers, nurses, nurse assistants, physiotherapists, occupational therapists and therapy assistants who were involved in the care and rehabilitation of the recruited patients also completed a questionnaire for each patient at the end of the respective three-month intervention periods (immediate and delayed groups).**

Data Analysis:

Descriptive statistics were used to describe patient characteristics (i.e., gender, side affected, type of stroke, age, time since onset). Data on wear compliance (reported on the wear-log) was presented as the number of days the sleeve was worn, mean hours per day and total number of hours worn over the 3-month period. For questionnaire data, descriptive analyses, including frequencies, proportions and measures of centrality and dispersion were used. For open-ended questions, synonym-based word frequency analysis was used [26]. When participants did not answer a specific question, their data for that specific question was omitted. **SPSS (version 26.0, IBM UK, Business Analytics, Middlesex, UK) was used for analysis.**

Results:

Over the one-year study duration, we approached 34 patients, of which 31 (91%) were recruited. Three patients declined participation due to other medical conditions. The randomisation assigned 19 patients to the immediate group and 12 to the delayed group. Table 1 shows the demographic characteristics of patients in each group.

A total of 27 patients, 19 (immediate) and eight (delayed) completed the questionnaire. Twenty-three carers/family-members and 36 healthcare staff (nurses (n=10), nursing assistants (n=5), physiotherapists (n=10), physiotherapy assistants (n=3) and occupational therapists (n=8) completed a questionnaire. Several staff reported for more than one patient resulting in up to 37 responses from nursing staff and 46 responses from therapy staff Table 2).

Daily sleeve wear was recorded on log-sheets and in total, **74% participants (n=20/27%)** returned log-sheets, of which only **20% (n=4/20)** had entries for the full 90 days (i.e. worn every day). The remaining **80% (n=16/20)** participants had entries for a median of 55 days with a range of 10-84 days. Across all returned log-sheets, mean duration of daily wear was 11 hours (range = 8-15 hours).

Of 27 participants, 88% (n=24) had no adverse effects and 12% (n=3) reported swelling in the hand/wrist. Staff groups noted slight temporary redness (**4% therapy staff, n=2/45**), discomfort at the wrist (**5% nurses, n=2/37**), itchy sensation (**3% nurses, n=1/37**), although these were not reported by patients. None of these caused discontinuity of wearing the sleeve.

Acceptability of Lycra Sleeve

The time taken to apply the sleeve was between two to five minutes as stated by majority of patients (**88%, n=22/25**), carers (**96%, n=21/22**), nurses (**97%, n=32/33**) and therapy staff (**97%, n=31/32**). The family members (**69%, n=16/23**), nurses (**73%, n=27/37**) and therapists (**85%, n=39/46**) felt the training provided was appropriate.

The sleeve was found to be comfortable by patients (**100%, n=27/27**). The use of the Lycra sleeve was acceptable in daily life by patients (**96%, n=24/25**), family member/carers (**96%, n=21/22**), nurses (**92%, n=34/37**) and in routine clinical practice by **physiotherapists/ occupational therapists and therapy assistants (91%, n=41/45)**. Getting the sleeve 'on' was considered easy by patients (**67%, n=18/27**), family members /carers (**79%, n=18/23**), nurses (**95%, n=34/36**) and

therapists (71%, n=32/45). Similarly, getting the sleeve 'off' was considered easy by patients (96%, n=26/27), family/members (96%, n=22/23), nurses (97%, n=35/36) and therapists (70%, n=32/46).

Sixty-three percent (n=17/27) of patients felt the sleeve made them more aware of the affected arm, and 67% (n=18/27) felt minimal or no shoulder looseness when the sleeve was applied. Seventy percent (n=19/27) of patients found the sleeve to be supportive and 60% (n=16/27) of patients were willing to wear the sleeve for longer term. Ninety two percent (n=24/26) of patients felt that the sleeve allowed them to participate in rehabilitation.

In comparison, 28% (n=13/46) of therapists felt that the sleeve improved the resting alignment, 54% (n=25/46) were neutral about this, whereas 18% (n=8/46) felt that the sleeve did not improve resting alignment. For longer term use, 37% (n=17/46) of therapists did recommend longer term use, while 49% (n=23/46) were neutral and 14% (n=6/46) would not recommend. Seventy percent (n=32/46) of therapists were neutral about the sleeve improving patients engagement in rehabilitation.

Discussion

The primary aim of this study was to explore patients', carers' and staff perceptions, regarding acceptability of wearing of Lycra sleeves over a three-month period in the **sub-acute** phase of stroke. **Findings suggest that a Lycra sleeve is acceptable to use from both patients, carer and staff perspectives.**

Participants completed diaries to record wear time of the Lycra sleeve, and 75% were returned. In agreement with previous studies [27], both the return and completion of diaries was lower than desired in our study. Patients in our study indicated that they wore the Lycra sleeve but struggled to record on the logbook. This could be attributed to cognitive and perceptual impairments [38], commonly seen in people with stroke, as well as additional time burden. To establish a possible effect of Lycra sleeve on UL impairments, accurate recording of wear time is necessary. Electronic monitoring using accelerometers may help overcome poor diary records, accurately determine wear fidelity and would be useful in the future trial [21]. This would remove data collection responsibility from the patient. In recent years, accelerometers have been found to be a reliable and valid way to monitor and gather physical activity data on gait, UL movements and functional tasks in people with stroke [29-31]. Accelerometers can continuously measure body movements based on accelerations over a long period in a home-based situation and are perceived as user friendly [29].

The majority of respondents reported no adverse effects of the Lycra sleeve and none mentioned were major or severe, supporting the safety and use of this sleeve in a stroke population in a phase II trial. Hand swelling, which has been recognised as an adverse effect in a similar study [21], was mentioned by 12% (n=3/27) of our participants, but in one case this related to use overnight against advice from researchers. Morris et al [21], used a custom-made longer garment which extended from metacarpophalangeal joints, including thumb, to deltoid insertion, but still had issues with hand swelling and pain, with three participants dropping out for these reasons, despite use of an additional hand compression glove. Gracies et al [20] in

their sleeve wearing study measured swelling specifically at fingers and forearm (finding improvement in both), they do not mention hand swelling as a result of wearing the sleeve but report good acceptance of their sleeve.

In this study, the Lycra sleeve was found to be acceptable by patients, carers and clinicians and was comfortable to wear as reported by all patients. **Additionally, 70% of patients found that the sleeve was supportive.** These findings on comfort and benefits are in agreement with a previous cross over study of 16 stroke patients that found Lycra sleeves to be comfortable [20]. In addition, that study (n=16) reported that a Lycra sleeve (from the wrist to the middle of the arm) worn over a 3-hr period improved wrist posture, reduced wrist and finger flexor spasticity, and resulted in a mean ($4.1^{\circ} \pm 13.0^{\circ}$) increase in passive range of movement at the shoulder joint (across all movements) [20]. **However, the majority (54%) of therapists in our study were neutral when asked if the wearing of a sleeve improved the resting alignment of the patient's affected arm, and, in the absence of evidence of effectiveness they were therefore not in favour of recommending the use of the sleeve for longer term.**

Participants in other studies have reported difficulty donning and doffing similar garments, particularly getting it over the hand and wrist [32-33]. In our study, the use of the applicator supplied with the sleeve was often beneficial and the majority of participants, carers and nurses reported that the time taken to apply the sleeve was \leq two minutes. A few participants reported to have taken a longer time initially to don the sleeve but then less time at a later date. This could be attributed to improvement

in donning technique or possible changes in integrity or elasticity of the garment, which was suggested by some participants.

This study had several limitations that need to be addressed in future studies. Firstly, one researcher (RJ) was a clinical therapist working at the hospital and could not be blinded. This researcher was involved with collection of questionnaire data. Therefore, measurement bias cannot be overruled. For the future, blinding the assessor to the groups would be vital to strengthen the validity of the study. Secondly, information about wear fidelity was limited due to unreliable and incomplete diary logs and this should be addressed in future studies using accelerometers.

Conclusion

In conclusion, this study suggests that the Lycra sleeve is acceptable by patients, carers and clinicians as a treatment for glenohumeral subluxation. However, research is required on the effectiveness and long-term benefits of the Lycra sleeve before this can be routinely used in clinical practice. Further research should also gather accurate information on wear fidelity of the Lycra sleeve using accelerometers.

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Declaration of Interest

The authors report no conflicts of interest. The authors are responsible for the content and writing of the article.

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Figure 1: Step-by-step application of the Lycra Sleeve using the orange applicator



**Table 1: Demographic characteristics of patients**

group	Immediate Group (n=19)	Delayed (n=12)
Gender, n (%)		
Male	14 (74%)	3 (33%)
Female	5 (26%)	8 (67%)
Age (Years), Mean (SD)	66 (14)	69 (17)
Type of Stroke, n (%)		
Haemorrhagic (%)	2 (11%)	0
Ischaemic (%)	17 (89%)	11 (92%)
Not-specified		1 (8%)
Hemiplegic Side, n (%)		
Right	5 (26%)	5 (44%)
Left	14 (74%)	7 (56%)
Hand Dominance, n (%)		
Right	17 (89%)	12 (100%)
Left	2 (11%)	
Time post stroke to randomisation, days, Mean (SD)	30 (27)	25 (16)
Median	8	25
Orthosis as routine treatment, n (%)		
Yes	7 (37%)	3 (25%)
No	12 (63%)	9 (75%)

SD- Standard Deviation, % -percentage

Table 2: Acceptability of Lycra sleeve, rehabilitation specific and training related questions for patients, carers/family, nurses and therapy staff

The sleeve was correct size	Acceptance of Lycra sleeve						
	Entirely Agree	Mostly Agree	Somewhat Agree	Neutral	Somewhat disagree	Mostly Disagree	Entirely disagree
1. Patients (27)	24 (88%)	1 (4%)		1 (4%)			1 (4%)
2. Family Members / Carers (23)	16 (70%)	6 (26%)	2 (5%)	2 (5%)	2 (5%)	1 (3%)	
3. Nurses (37)	23 (62%)	7 (19%)	1 (2%)	6 (13%)	3 (7%)	1 (2%)	1 (2%)
4. Therapy staff (46)	20 (44%)	14 (30%)					

Putting on the sleeve was

easy							
1. Patients (27)	13	1 (4%)	4 (15%)	1 (4%)	5 (18%)	1 (4%)	2 (7%)
2. Family Members / Carers (23)	(48%) 8 (36%)	7 (30%)	3 (13%) 5 (14%)	3 (13%)	1 (4%) 2 (5%)	1 (4%)	
3. Nurses (36)	19	10	7 (16%)		1 (2%)	1 (2%)	
4. Therapy staff (45)	(53%) 13 (28%)	(28%) 12 (27%)		11 (24%)			
Taking off the sleeve was easy							
1. Patients (27)	24	1 (4%)	1 (4%)		1 (4%)		
2. Family Members / Carers (23)	(88%) 14 (61%)	6 (26%)	2 (9%) 1 (3%)	1 (4%)	1 (3%)		
3. Nurses (36)	6	4 (9%)		14			
4. Therapy staff (46)	28 (78%) 22 (48%)	6 (16%) 6 (13%)		30 (30%)			
The sleeve allowed to engage in daily activities							
1. Patients (27)	15	4	2 (7%)	4		1 (4%)	1 (4%)
2. Family Members / Carers (22)	(55%) 16 (74%)	(15%) 3 (14%)	1 (4%) 4 (11%)	(15%) 1 (4%)	1 (3%)	2 (5%)	1 (4%)
3. Nurses (37)	6			6 (16%)			
4. Therapy staff (45)*	18 (49%)	6 (16%)					
Use of the Lycra sleeve is acceptable in daily life / in routine clinical practice*							
1. Patients (25)	17	7		1 (4%)			
2. Family Members / Carers (22)	(68%) 16 (74%)	(28%) 4 (18%)	1 (4%) 2 (5%)	1 (4%) 2 (5%)		1 (3%) 1 (2%)	
3. Nurses (37)	5		5 (11%)	3 (7%)			
4. Therapy staff (45)*	22 (60%) 26 (58%)	10 (27%) 10 (22%)					
25 (93%)	2 (7%)						
The sleeve was comfortable to wear - Patient (n=27)							
Therapy specific – Patient / Therapist evaluation							
	Entirely Agree	Mostly Agree	Somewhat Agree	Neutral	Somewhat disagree	Mostly Disagree	Entirely disagree
The sleeve was beneficial - Patient (26)	4 (16%)	5 (19%)	1 (4%)	10 (38%)		1 (4%)	5 (19%)
The sleeve made me aware of the affected arm Patient (27)	13 (48%)	1 (4%)	3 (11%)	3 (11%)	1 (4%)	4 (15%)	2 (7%)
I felt minimal or no shoulder looseness when the sleeve was applied – Patient (n27)	15 (56%)	3 (11%)		7 (25%)	1 (4%)		1 (4%)
Sleeve allowed me to participate in rehabilitation / to engage more with the arm during rehabilitation*							
1. Patients (26)	19	2 (8%)	3 (11%)	1 (4%)			1 (4%)
2. Therapy staff (46)*	(73%) 1 (2%)	4 (9%)	1 (2%)	32 (70%)	3 (7%)	2 (4%)	3 (7%)
The sleeve provided support to my affected arm / The sleeve improved the resting alignment of the patient's affected arm*							
Patient (27)	7 (26%)	8 (29%)	4 (15%)	3 (11%)	1 (4%)	1 (4%)	3 (11%)
Therapist (46)	1 (2%)	4 (9%)	8 (17%)	25 (70%)	1 (2%)	4 (9%)	3 (7%)

(54%)							
I would be willing to wear the sleeve for longer term / would recommend the sleeve for longer term use*							
Patient (27)	11	3	2 (7%)	2 (7%)	3 (11%)	1 (4%)	5 (18%)
Therapist (46)*	(42%) 6 (13%)	(11%) 4 (9%)	7 (15%)	23 (49%)		3 (7%)	3 (7%)
Training related: Staff / Family members							
You received appropriate training for the application of sleeve	Entirely Agree	Mostly Agree	Somewhat Agree	Neutral	Somewhat disagree	Mostly Disagree	Entirely disagree
2. Family Members / Carers (23)	13 (56%)	3 (13%)	4 (11%)	3 (13%)	4 (11%)	2 (9%)	2 (9%) 3 (8%)
3. Nurses (37)	22 (59%)	1 (3%)	8 (17%)	3 (8%)	2 (4%)	1 (2%)	
4. Therapy staff (46)	20 (43%)	11 (24%)		4 (9%)			
The information provided for the application of sleeve was clear							
2. Family Members / Carers (23)	17 (75%)	3 (13%)	1 (4%) 6 (16%)	1 (4%) 1 (3%)			1 (4%) 2 (5%)
3. Nurses (37)	21 (57%)	7 (19%)	6 (13%)	3 (7%)		1 (2%)	
4. Therapy staff (45)	19 (42%)	16 (36%)					

Four questionnaires were developed that had common questions for patients/Family members-carers/staff and few specific questions to patients / therapists and these are reflected in the table. Nurses (10), nursing assistants (5), physiotherapists (10), physiotherapy assistants (3), occupational therapists (8) were involved and (n) responses relates to more than 1 staff providing feedback for the each patient.