



EFFECTIVENESS OF A STRUCTURED SEXUAL REHABILITATION PROGRAMME FOLLOWING STROKE: A RANDOMIZED CONTROLLED TRIAL

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Background: Sexual activity is an integral part of life; it is important to address sexual health after stroke, but this is often poorly done.

Objective: To assess the effectiveness of a structured sexual rehabilitation programme compared with written information alone regarding sexual and psychological functioning (anxiety, depression, stress), functional independence and quality of life in an Australian stroke cohort.

Methods: A total of 68 participants were randomized to a structured sexual rehabilitation programme (treatment group; $n=35$) or to written information alone (control group; $n=33$). Outcome measures included: Sexual Functioning Questionnaire Short Form; Depression, Anxiety Stress Scale; Functional Independence Measure, and Stroke and Aphasia Quality of Life Scale-39 Generic. Assessments were performed at baseline, 6 weeks and 6 months after the intervention. Participant's preferences regarding how they would like to receive information, who from, and how frequently, were collected at baseline.

Results: There was no difference between groups for any outcome measures. Half of the participants (51%) wished to receive information and were divided equally into preferring written information vs face-to-face counselling, with the majority (54%) preferring information after discharge from an inpatient setting.

Conclusion: Provision of written information alone appears to be as effective as a 30-min individualized sexual rehabilitation programme in an inpatient setting. Further research is needed regarding longer term outcomes and outpatient settings.

Key words: sexual dysfunction; stroke; rehabilitation; sexuality; counselling.

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Stroke is a leading cause of death and disability (1). Sexual dysfunction is common after stroke, and has multifactorial causes: damage to the brain (causing decline in sexual desire/interest and coital frequency for both sexes, decline in vaginal lubrication and orgasm in

females, and in erection and ejaculation in males, and physical changes, such as hemiplegia with resulting impairment of mobility) together with medical issues, such as medications and premorbid medical conditions (diabetes, hypertension, cardiac issues) and psychological factors (fear of new stroke, loss of self-esteem, role/relationship changes) are major contributors (2–5).

Sexuality is a broad concept and may be experienced and expressed in a variety of ways; including thoughts, fantasies, desires, beliefs, attitudes, values, behaviours, practices, roles, and relationships (6). Sexual activity is an integral part of life and the importance of addressing sexual health after stroke is well accepted (7). Despite this, it is common for sexuality to be poorly addressed, not just in stroke, but also in other neurological conditions, such as spina bifida (8) and spinal cord injury (9). The 2012 Australian National Stroke Audit Rehabilitation Services Report (10), which included 2,789 post-stroke patients across 111 Australian public and private hospitals, showed that only 17% of patients received information on sexuality. This is despite the opportunities provided through the staffing complement in rehabilitation settings. In practice, allied healthcare providers could have a primary or secondary role in sexual rehabilitation; they could be the sole providers of intervention or provide further intervention in their specific areas of expertise, such as physiotherapy training to optimize mobility in bed for sexual positioning, nursing education for catheter management, and dyspraxia training with speech therapy for sexual activities such as kissing. In addition, although current guidelines recommend the assessment and management of post-stroke sexual dysfunction (7), it is unclear what types of intervention (timing, content, intensity, setting) should be provided and how effective they are. The only intervention study currently available in the literature that addresses the impact of intervention on sexual activity following stroke suggests that a sexual rehabilitation intervention programme prior to hospital discharge increased sexual satisfaction and frequency of sexual activity one month post-discharge, but did not promote sexual knowledge (11). This study was conducted with culturally homogenous 40–49-year-old Korean couples and had significant methodological limitations (generalizability, pre-post design, and short follow-up). Patient's preferences relating to sexual counselling, such as the

timing of such counselling, also varied, creating further challenges for optimization of care (12, 13). Some studies show that most participants feel overwhelmed in the early adjustment period and that the best time to address sexual adjustment issues is towards the end of an acute rehabilitation hospitalization or shortly after discharge. In a pilot randomized controlled trial (RCT) conducted in 2014, the feasibility and importance of providing sexual rehabilitation following stroke was demonstrated; however, the “pilot” nature of the study did not allow for conclusive findings to be drawn (14).

The primary aim of this RCT was to assess the effectiveness of a comprehensive structured sexual rehabilitation programme compared with written information alone, on sexual and psychological (anxiety, depression, stress) function, and on functional independence and quality of life in an Australian stroke cohort. Building on the previous pilot RCT, to our knowledge this will be the first adequately powered RCT in this area. The findings will provide evidence that may lead to improved care.

METHODS

This RCT followed the CONSORT criteria and was approved by the Melbourne Health Ethics Committee (HREC 2013.216).

Participants and setting

The study was conducted over 14 months (Feb 2014 to April 2015) in the stand-alone 35-bed inpatient rehabilitation unit at Royal Melbourne hospital (RMH), a tertiary referral centre in Victoria, Australia. Approximately 100 stroke patients are admitted annually, with a mean length of stay 6 of 3 weeks. Patients receive individualized medical and nursing care and 2–3 h of therapy daily from allied health disciplines (including occupational therapy, physiotherapy, speech therapy, social work, psychology, neuropsychology, dietetics). Functional Independence Measure (FIM) is routinely collected on admission and discharge.

The inclusion criteria were: confirmed diagnosis of stroke (haemorrhagic or ischaemic) based on clinical examination and imaging, as assessed by a neurologist, ability to comprehend (FIM comprehension score ≥ 4), ability and willingness to give informed consent, and age 18 years and above. Exclusion criteria were: severe cognitive issues (FIM cognition ≤ 4), dementia or unstable medical conditions precluding participation in a sexual rehabilitation programme, and inability to source an interpreter for those who were unable to speak English. All consecutively admitted patients were screened within one week of admission and those who met the inclusion criteria were invited to participate in this study by a primary researcher (LN or NZ, not their treating physician) who explained the study and sought informed consent.

Procedure

Following consent, participants were randomized to control or treatment groups using a computer-generated sequence by an independent statistician. Consecutively numbered, opaque, sealed envelopes were used for allocation concealment. Participants were free to withdraw from the study at any stage.

All baseline patient assessments were completed on the ward within 1 week of admission by researchers who had received training in all assessments. These blinded assessors (JS, JY) did not have access to previous assessments, patient treatment schedules or treating rehabilitation therapy team documentation. Baseline assessments included socio-demographic and clinical information, a short survey adapted from Stein 2013 (13) on participant preference on timing of counselling, means of information delivery, preferred type of healthcare provider for counselling, and importance of sexual issues, and measures of impairments, disability and health-related quality of life measures using standardized instruments (see measures). In order to avoid recall bias participants were asked to respond based on their current (in-hospital) status. The assessors did not prompt participants, but provided physical assistance for completion of forms as required. Assessment time-points were: baseline, 6 weeks and 6 months following intervention (intervention group) and 6 weeks and 6 months following discharge for the control group.

The treatment group received a 30-min individualized sexual rehabilitation programme and the offer of a more comprehensive intervention towards the end of their inpatient stay in addition to written educational material (factsheet produced by the National Stroke Foundation) (15) on “sexuality after stroke”, which was provided at the time of recruitment. The programme consisted of a single stand-alone 30-min individualized session in the inpatient setting conducted by their rehabilitation physician (LN or NZ, both trained through the Australasian Faculty of Rehabilitation Medicine and with 7 years of experience in delivery of sexual rehabilitation) with the offer of additional input from occupational therapy, physiotherapy and or psychology as required, for counselling or training to optimize bed mobility for sexual positioning or addressing other aspects of sexuality. Sexual partners of participants were offered participation in the sessions with the consent of the participants where possible/available. Programmes were individually tailored and based on the PLISSIT model (16) (Permission (reassurance that sexual dysfunction is common), Limited information (such as safety of resuming sexual activity), Specific Suggestions (such as positioning), and Intensive Therapy (such as in-depth counselling). Intensive therapy was not provided as part of the 30-min session, but participants could be referred where deemed appropriate by the participant and physician. Content was similar to previously described sexual rehabilitation programmes (11) and included: (i) provision of information regarding common changes in sexuality post-stroke; (ii) counselling on fears regarding post-stroke sexuality; (iii) challenging stereotypical views on sexuality and sexual satisfaction (such as sexual intercourse being the only expression of sexual activity, having sexual intercourse only at night or that sexual intercourse must be spontaneous to achieve sexual satisfaction); (iv) provision of tips and strategies to minimize post-stroke sexual dysfunction, such as choosing a suitable time, reviewing sexual side-effects from medications, finding safe and comfortable sexual positions, managing reduced vaginal lubrication, urinary continence issues, or erectile difficulties. The control group received the written education material only at the time of recruitment, but were allowed to request further information to ensure they were not unduly disadvantaged in their clinical care.

Measurements

Sexual Functioning Questionnaire Short Form (CSFQ-14) is a self-assessment tool in which the patient is asked to evaluate his or her current sexual behaviour (including masturbation, sexual

thoughts) and issues. The questionnaire consists of 14 questions, using a 5-point scale, in 5 subscales covering 3 domains corresponding to the phases of the sexual response cycle (desire, arousal and orgasm). A total score is obtained by summing the values of items 1–14. Scores ≤ 41 for females and ≤ 47 for males indicate sexual dysfunction according to Keller et al. (17). Each participant was provided with the appropriate sex-specific version. CSFQ-14 has good validity as a global measure of sexual dysfunction and strong internal reliability (17).

Depression, Anxiety Stress Scale (DASS) (18) is a 21-item instrument, consisting of 3 7-item self-report scales designed to measure the negative emotional states of depression, anxiety and stress. Participants rate the extent to which they experienced each state over the past week on a 4-point Likert rating scale. It has acceptable to excellent internal consistency and concurrent validity.

Functional Independence Measure (FIM) (19) is widely used internationally in rehabilitation settings to assess function and need for assistance. The FIM motor section has 13 items that assess level of function in 4 subscales: Self-care, Transfers, Locomotion and Sphincter control, rating on a scale of 1–7 (1 = total assistance, 7 = independent). FIM has good reported reliability and validity (19).

Stroke and Aphasia Quality of Life Scale-39 Generic (SAQOL-39g) is a stroke-specific scale which has been validated on patients with and without aphasia (20). There are 39 items, on a scale of 1–5, in 3 categories: physical, psychosocial and communication. The SAQOL-39 has good test–retest reliability, internal consistency and construct validity (21).

Statistical analysis

The primary outcome for this study was defined as the impact of the intervention on sexual function, as assessed using CSFQ-14. There is no information regarding the “minimal clinically important difference” for CSFQ-14 in current literature, therefore a change of 5 points or greater from baseline to 3 months was considered clinically relevant. An overall sample of 60 participants (30 participants in each arm) were required to provide 80% power to detect a change of 5 points from baseline to 3 months, between intervention and control group (2-sided $\alpha=0.05$).

Standard principles for RCTs were followed for analyses on the scales and scores of the measurement tools. Data on patient demographics and disease characteristics were presented in a descriptive manner with numbers and percentages. The main analysis examined changes in the outcome measures over time (pre (T1) – 3-month follow-up (T2) and pre (T1) – 6-month follow-up (T3)) between the control and intervention groups, using Mann-Whitney *U* tests. Clinically important changes were estimated as effect size (*r*), which was calculated and assessed against Cohen’s

criteria (0.1–0.29 = small, 0.3–0.49 moderate and ≥ 0.5 = large effect). A *p*-value < 0.05 was considered statistically significant. Analyses were on an intention-to-treat basis, with participants assigned according to their initial allocation irrespective of their subsequent compliance with the protocol. All analyses were completed using IBM SPSS Statistics Package Version 21 (22).

RESULTS

Of the 130 stroke patients admitted during the study period, 111 met the inclusion criteria. Forty-three (38.7%) declined to participate, mostly stating that sexuality was not relevant to them, and 68 agreed to participate (Fig. 1). Twenty-one were excluded due to severe cognitive/communication difficulties ($n=19$) or lack of interpreter availability for non-English speakers ($n=2$). Of the 68 participants at baseline, 35 were allocated to intervention and 33 to control. Five participants in the treatment group and 3 participants in the control group dropped out at the 6-week follow-up and a further 5 participants in the treatment group and 4 in the control group dropped out at 6 months, leaving 51 in total (25 in the intervention group, 26 in the control group). Most of the drop-outs were due to

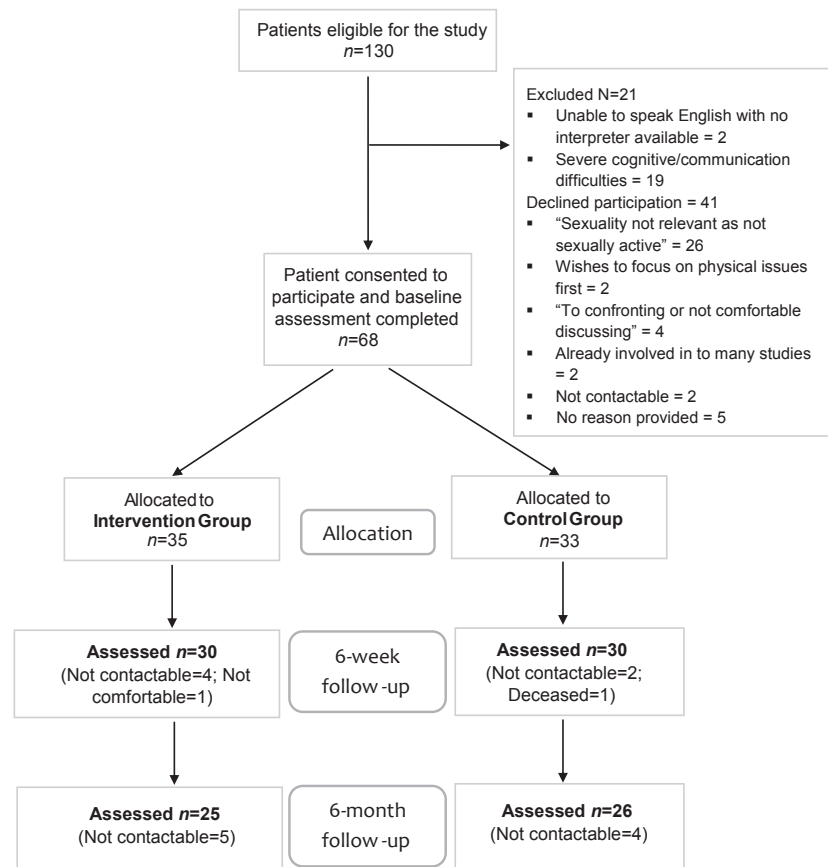


Fig. 1. Participant flow through the study.

participants not being contactable. Socio-demographic and clinical baseline characteristics for participants are summarized in Table I and there were no statistical differences between the groups.

The mean age of participants was 63.3 years (standard deviation 17) (range 19–95 years) and 57% were male. Baseline demographic and medical characteristics were similar across treatment arms. Forty of the 68 participants (24 in the intervention group, 16 in the control group) reported not having had sexual intercourse for at least 5 years prior to the stroke, but were still sexually active in terms of the broader definition of sexuality (masturbation, sexual thoughts, enjoying films with sexual content, etc.). Twenty-nine participants had a formal partner; however, this did not correlate with being sexually active in terms of having sexual intercourse. They remained, however, “sexual partners”, using the broader definition of sexuality. The large majority of participants ($n=54$, 79.4%) had sexual dysfunction at baseline, as measured by the CSFQ-14. Half (51%) of the patients reported that sexuality was an important issue (Table II).

Of the participants who deemed sexuality “important”, half preferred a “pamphlet”, whilst the other

half preferred “one-on-one discussion” with their doctor. A third of participants wanted information before discharge, whilst the majority of participants (54%) preferred information after discharge. For those who wished to have information (55% of total cohort), two-thirds preferred a “one-off” information session, whilst the remaining third (17% of total cohort) wished to have 3 or more sessions.

In terms of intervention provided, participants in the intervention group tended to largely listen and/or read the written information provided at the time of recruitment and posed no questions during the 30-min one-on-one session they received. Participants in the control group only read the information provided and none requested the one-on-one sessions offered or any additional information. None of the sexual partners who were offered participation in discussions on sexuality with the treating physicians chose to do so. No additional input was sought from allied health providers relating to more comprehensive sexual rehabilitation. No medications for sexual dysfunction were prescribed, as the physician did not judge these to be relevant at the time of the patient’s inpatient rehabilitation stay.

Change scores (baseline minus post-treatment) for all outcome measures were calculated for the treatment and control groups (Table III).

Table I. Socio-demographic characteristics of the participants ($n=68$)

Characteristics	Intervention group $n=35$	Control group $n=33$
Age, years, mean (SD) [range]	62.0 (17.3) [19–88]	66.8 (16.7) [24–95]
Male, n (%)	21 (60.0)	18 (54.5)
Married/formal partner, n (%)	17 (48.6)	12 (36.4)
Language English, n (%)	27 (79.4)	28 (84.8)
Education secondary/tertiary, n (%)	26 (76.5)	26 (80.7)
Stroke type ischaemic, n (%)	28 (80.0)	26 (78.8)
Dominant hemisphere, n (%)	18 (52.9)	13 (40.6)
Previous history of stroke, n (%)	9 (25.7)	4 (12.1)
Currently on medication, n (%)	32 (91.4)	27 (81.8)
SSRI/anti-depressants	3 (8.6)	6 (13.2)
Beta-blockers	8 (22.9)	7 (21.2)
Anti-hypertensives	21 (60.0)	19 (57.6)
Co-morbidities, n (%)	30 (85.7)	26 (78.8)
Hypertension	15 (42.9)	17 (53.1)
Diabetes	9 (25.7)	9 (28.1)
Coronary heart disease	6 (17.1)	5 (15.6)
Hyperlipidaemia	8 (22.9)	7 (21.9)
Symptoms, n (%)		
Sensory deficit	12 (34.3)	19 (57.6)
Hemiplegia	28 (80.0)	27 (81.8)
Language deficit	20 (57.1)	16 (48.5)
DASS, n (%)		
Depression		
Normal/Mild	28 (80.0)	29 (87.9)
Moderate – Extremely severe	7 (20.0)	4 (12.1)
Anxiety		
Normal/Mild	27 (77.1)	26 (78.8)
Moderate – Extremely severe	8 (22.9)	7 (21.2)
Stress		
Normal/Mild	30 (85.7)	29 (87.9)
Moderate – Extremely severe	5 (14.3)	4 (12.1)

DASS: Depression Anxiety Stress Scale; IQR: interquartile range; SD: standard deviation; SSRI: selective serotonin re-uptake inhibitors.

Table II. Patient preferences for post-stroke sexual rehabilitation

Characteristics	Study population n (%)
Importance of sexual rehabilitation ($n=67$)	
Not important	32 (47.8)
Important	19 (28.3)
Very important	16 (23.9)
Sexual rehabilitation media ($n=65$)	
Pamphlet	14 (21.5)
1–1 discussion	18 (27.7)
Group session	1 (1.5)
Internet	4 (6.2)
Does not wish to receive	28 (43.1)
Rehabilitation provider ($n=65$)	
Doctor	26 (40.0)
Other healthcare professionals	7 (10.8)
Does not wish to receive	32 (49.2)
Timing of rehabilitation ($n=62$) ^a	
Weekend before discharge	7 (11.3)
Before discharge	12 (19.4)
Within 3 months of discharge	15 (24.2)
Within 6 months to 1 year of discharge	18 (29.0)
Does not wish to receive	24 (38.7)
Rehabilitation information preference ($n=58$) ^b	
Safety of resuming sexual activity	12 (20.7)
Common sexual problems post-stroke	8 (13.8)
Adaptive measures	4 (6.9)
Does not wish to receive	26 (44.8)
Frequency of sexual rehabilitation ($n=65$)	
None	33 (50.8)
Once	18 (27.7)
Twice	3 (4.6)
Three or more	11 (16.9)

^aSome patients chose more than one option.

^bSome patients did not pick any options provided.

Table III. Change scores in measurement scales over time

Scales	Intervention group (median, IQR)			Control group (median, IQR)			T2-T1			T3-T1		
	T1 (baseline) (n=35)	T2 (6 weeks) (n=30)	T3 (6 months) (n=25)	T1 (baseline) (n=33)	T2 (6 weeks) (n=30)	T3 (6 months) (n=26)	z	p	r ^a	z	p	r ^a
CFSQ												
Total	24 (17, 41)	26 (16.8, 39)	26 (16.5, 36.5)	26 (17, 34.5)	28 (16, 40)	35 (18.5, 41)	-0.31	0.758	0.04	-1.11	0.266	0.16
Pleasure	1 (1, 3)	1 (1, 3)	2 (1, 3)	1 (1, 3)	1 (1, 3)	2 (1, 4)	-0.68	0.495	0.09	-0.31	0.761	0.04
Frequency	4 (2, 6)	2 (2, 6)	4 (2, 6)	3 (2, 5)	4 (2, 6)	5 (2, 6)	-1.09	0.274	0.14	-0.37	0.715	0.05
Interest	4 (3, 10)	5.5 (3, 9)	7 (3, 9)	6 (3, 9)	6 (3, 9)	7 (4.5, 9)	-0.36	0.721	0.05	-0.41	0.684	0.06
Arousal	6 (3, 11)	6 (3, 11)	3 (3, 9.5)	5 (3, 9)	7 (3, 9)	8 (3, 9)	-0.42	0.672	0.05	-2.22	0.027*	0.31
Orgasm	4 (3, 11)	5 (3, 11)	6 (3, 10)	5 (3, 10)	7 (3, 11)	8 (3, 11)	-0.14	0.887	0.02	-0.86	0.388	0.12
FIM Motor												
Total	56 (31.5, 71.5)	86 (71, 91)	86 (66.5, 86)	57.5 (45.8, 77.6)	88.5 (81, 91)	87.5 (81, 91)	-0.28	0.779	0.04	-0.4	0.968	0.06
Self-care	25 (14.8, 32.5)	42 (30.8, 42)	42 (28, 42)	27 (20.5, 27)	38.6 (35.1, 42)	42 (39, 42)	-0.31	0.975	0.04	-0.38	0.704	0.05
Sphincter	13 (9.5, 13)	14 (13, 14)	14 (13, 14)	13 (12, 13)	14 (14, 14)	14 (14, 14)	-0.27	0.789	0.03	-0.58	0.566	0.08
Mobility	12 (5.3, 18)	21 (18, 21)	21 (15, 21)	13 (9, 18)	21 (18, 21)	21 (18, 21)	-0.51	0.610	0.07	-0.01	0.992	0.00
Locomotion	3.5 (2, 7)	12 (9.5, 14)	13 (7, 14)	5 (2, 9)	13 (10, 14)	12 (9.6, 14)	-0.33	0.737	0.04	-0.76	0.449	0.11
FIM Cognition												
Total	27 (21.8, 32.5)	35 (27.5, 35)	35 (32.5, 35)	29.5 (23, 34)	35 (32.6, 35)	35 (32.5, 35)	-0.25	0.803	0.03	-0.01	0.992	0.00
Communication	11 (9, 14)	14 (11, 14)	14 (13, 14)	12 (10, 14)	14 (14, 14)	14 (13, 14)	-0.23	0.816	0.03	-0.39	0.695	0.05
Psychosocial	6 (5, 6)	7 (6, 7)	7 (6, 7)	6 (5, 7)	7 (6, 7)	7 (6, 7)	-0.41	0.684	0.05	0.00	1.00	0.00
Cognition	10.5 (6.8, 14)	14 (10, 14)	14 (13, 14)	12 (8.3, 12)	14 (12.6, 14)	14 (12.3, 14)	-0.82	0.415	0.11	-0.56	0.576	0.08
DASS												
Total	8 (4, 32)	17 (5.5, 32)	14 (0, 42)	12 (6, 31)	14 (2, 24)	14 (3, 24)	-0.91	0.366	0.12	-0.72	0.472	0.10
Depression	2 (0, 8)	4 (0, 14)	4 (0, 14)	4 (2, 9)	2 (0, 9)	2 (0, 10)	-1.14	0.255	0.15	-0.49	0.626	0.07
Anxiety	2 (0, 8)	5 (0, 9)	4 (0, 9)	4 (0, 8)	2 (0, 6)	2 (0, 5)	-0.68	0.497	0.09	-0.86	0.390	0.12
Stress	4 (2, 10)	5 (0, 12.5)	6 (0, 15)	6 (2, 15)	2 (0, 10)	4 (0, 11)	-1.18	0.240	0.15	-0.34	0.738	0.05
SAQOL												
Total	3.6 (3.2, 4.3)	4.1 (3.5, 4.7)	3.8 (3.2, 4.7)	3.8 (3.2, 4.6)	4.5 (3.7, 4.7)	4.4 (3.7, 5)	-0.41	0.682	0.05	-0.04	0.969	0.01
Physical	3.8 (2.8, 4.5)	4.2 (3.4, 4.9)	4.2 (3.1, 4.9)	4.4 (3.6, 4.4)	4.8 (3.8, 5)	4.6 (3.8, 5)	-0.59	0.554	0.08	-0.24	0.808	0.03
Communication	4.4 (3.6, 5)	4.7 (3.8, 5)	4.7 (3.3, 5)	4.9 (4.1, 5)	5 (4.6, 5)	5 (4.7, 5)	-0.23	0.822	0.03	-0.28	0.780	0.04
Psychosocial	3.6 (3.1, 4.1)	3.9 (3.2, 4.7)	3.6 (2.9, 4.8)	3.6 (3.0, 4.3)	4 (3.3, 4.7)	4.4 (3.2, 5)	-0.69	0.490	0.09	-0.07	0.946	0.01

* $p < 0.05$.^aEffect size statistics (r) were calculated and assessed against Cohen's criteria (0.1 = small, 0.3 = medium, 0.5 = large effect).

CSFQ: Changes in Sexual Functioning Questionnaire (Short); DASS: Depression Anxiety Stress Scale; FIM: Functional Independence Measure; IQR: interquartile range; SAQOL: Stroke and Aphasia Quality Of Life Scale; IQR: interquartile range.

At the 6-week follow-up, there was no significant improvement in the intervention group compared with the control group in CFSQ-14, DASS, FIM or SAQOL. At 6-month follow-up, there were no significant differences between the intervention group compared with the control group in CFSQ-14, DASS, FIM or SAQOL, except for the subscale of CSFQ Arousal, which was improved in favour of the control group (with moderate effect size $r=0.3$).

DISCUSSION

As far as we are aware, this is the second RCT of a post-stroke sexual rehabilitation programme, building on an initial pilot feasibility RCT (14). Results found that an individualized 30-min sexual rehabilitation session in addition to generic written information on post-stroke sexuality, compared with written information alone, is *equally* effective in improving outcomes of sexual functioning, psychological coping and quality of life in the short (6 weeks) and medium (6 months) term. In terms of participant preferences, there appears to be an equal split of preference for written information vs face-to-face counselling and the majority prefer information after discharge from inpatients, potentially repeated

over time. Participants in this study were similar to those in other post-stroke participants in terms of age, sex, and clinical characteristics (23, 24).

Through a pre-post intervention study, Song et al. found that a sexual rehabilitation programme consisting of counselling improved sexual satisfaction and frequency of sexual activity (11). In addition, this RCT has found that written information appears to be as effective as a 30-min counselling and written information. The reasons for this are probably multifactorial. Written information was provided to both groups at the time of recruitment (which occurred soon after admission); however, the counselling session did not occur until towards the end of their admission. Participants therefore had time during their admission to read through the written material, which, whilst generic in nature, was comprehensive and probably covered the information they would have sought during counselling anyway. The rehabilitation physicians providing the counselling sessions noted that most patients were happy to have counselling, but did not ask questions. In addition, a larger proportion of participants in the intervention group were not sexually active in terms of partner intercourse, which would have limited the overall ability to demonstrate effectiveness of the

intervention and on improvements in sexual function; hence improvement in the CSFQ-14 Arousal subscale in favour of the control group.

The overall low prevalence of sexual intercourse activity (41%) amongst the participants prior to their stroke is consistent with cohort studies within the older Australian population. Hyde et al. (25) found that, within community-dwelling men aged 75–95 years in Western Australia, only 30.8% had had at least 1 sexual encounter in the past 12 months (25). In contrast, Bretchneider & McCoy (26) studied healthy residents of Californian retirement homes aged 80–102 years and found that 62% of men and 30% of women had had recent sexual intercourse, while 87% of men and 68% of women had had physical intimacy of some sort. Helgason and colleagues studied 319 Swedish men and found that 46% of the oldest men (aged 70–80 years) reported having orgasms at least once a month (27). Hence it is likely that a similar sexual rehabilitation programme would have demonstrated overall more effectiveness in cohorts with higher levels of sexual activity. The low level of sexual intercourse activity probably also explains the lack of interest in involvement from the participants' partners in counselling. In addition, sexual rehabilitation was offered rather than recommended to the partners. They may have been more willing to engage if it had been a strong recommendation from the medical staff.

This study also highlighted the gap in current tools for screening and outcome measurement. The study suggests that, regardless of relationship status, patients should be offered the opportunity to receive information, which is consistent with the recommendations made by the National Stroke Foundation (7). At present there are no screening tools for sexuality for the stroke population, although one has been proposed for female sexual dysfunction in the general population (28). In addition to the lack of screening tools, outcome measurement for sexuality is problematic. This study utilized the CSFQ-14 as the measurement outcome for sexual dysfunction in the participants. This is a widely used tool that addresses sexual satisfaction, sexual dysfunction and distressing dysfunction, and was initially developed for use in measuring sexual dysfunction and sexual side-effects of psychotropic medications (17). Whilst the CSFQ-14 has previously been used in other stroke studies (13), it has not been validated in the stroke population and is probably not sensitive enough or adequately targeted for this population; for example, the effects of hemiplegia or language deficits are not considered within the questionnaire. There are also ceiling effects in many of the available measures, including the CSFQ-14. The development of a more

comprehensive, stroke-specific tool is needed for more accurate and responsive data.

The clinical implications of this study include:

- Timing of sexual rehabilitation is important. Consistent with other studies (29), many patients feel overwhelmed in the early stages of stroke recovery and rehabilitation and prioritize physical functioning. General counselling is advised to assist patients and their partners with general coping. Closer to discharge home, or even following discharge home, sexual issues may then become more of a priority for both the patient and their partner. In a rehabilitation unit, where acuity of stroke has increased considerably over time (patients move to rehabilitation units days, as opposed to weeks, after a stroke), this becomes even more relevant. It appears that it is useful for initial information to be provided to patients prior to discharge; however, for a proportion of patients (17% in this study), subsequent follow-up is required based on patient preferences.
- Initial information in the form of written information appears to be as effective as more time and resource-intensive one-on-one counselling. It is therefore suggested that all patients be given written information with an offer of counselling on request. Patients who have difficulty understanding written information (such as those speak other languages, or have dysphasia or cognitive issues) should be provided with appropriately facilitated face-to-face counselling.

As a further consideration, although this study actively offered the option of involving allied health disciplines in the sexual rehabilitation programme, these services were not sought. Anecdotally, the role of allied health providers within an interdisciplinary rehabilitation team is significant given their areas of expertise; allied health providers also often form close relationships with patients given their high contact time. This is not reflected, however, in the findings of this particular study. The lack of input from allied health providers in this study is most likely explained by many participants declining sexual rehabilitation overall and the patients who received the intervention having relatively simple needs that could be met through either written information or counselling by medical staff alone. Notably, the study facility did not have a sexual counsellor on staff whose professional input would be useful. In addition, many patients are on medications that could affect male erectile dysfunction, and this should be addressed as part of a sexual rehabilitation programme in patients following stroke. In this study, no medications were prescribed or ceased in relation to sexuality. This may be more relevant at a later time and, anecdotally, phosphodiesterase inhibi-

tors, for example, tend to be prescribed in an outpatient setting (as opposed to inpatient setting). Clinicians may also reconsider ceasing or changing antidepressants, such as selective serotonin reuptake inhibitors, if these medications were negatively impacting on sexual function.

The limitations of this study include: (i) selective cohort from a single centre; however, the cohort represented a broad age-range, socio-demographic and cultural background and is therefore generalizable, at least in Australia, to other rehabilitation centres; (ii) a broad definition of sexuality was used, which could have limited the overall ability to demonstrate effectiveness of the intervention itself; however, this is more representative of post-stroke cohorts; (iii) few willing research participants; (iv) exclusion of those with severe dysphasia/cognitive issues who form a small, but significant, proportion of the stroke population. Interviews were challenging given the personal nature of the questions that may have resulted in some participants not providing accurate responses. Information was validated as best with caregivers and medical records. (v) It should also be noted that to avoid recall bias, participants were asked to rate their “current” (i.e. in hospital) sexual behaviour, where there may be reduced opportunities for partner sexual intercourse. However, given that a broad definition of sexuality was used (including masturbation and sexual thoughts), and that partner sexual intercourse activity was low, assessments were probably reasonably accurate.

This study also highlights common confounders in rehabilitation research. The complexity and heterogeneity of stroke itself and sexual rehabilitation as an intervention and the effect of individual intervention makes such an intervention challenging to study within a traditional RCT research design and increases the difficulty of being able to answer the questions are that posed. An alternative approach is through “clinical practice trials”, which acquire prospective and retrospective data without disrupting the natural milieu of treatment (30, 31). Through routine data collection, additional information about the nature of services provided, outcomes of rehabilitative care and implications for clinical practice is gathered and can provide answers to optimal models of care (32). Such approaches have been used in the multiple sclerosis population to quantify intensity of rehabilitation intervention in inpatient rehabilitation programmes and to determine patient complexity and the need for therapy.

There is a paucity of literature addressing sexual rehabilitation post-stroke. This study represents a small, but significant, step towards better understanding of optimal management of sexual needs for patients after stroke. Further studies, with consideration of more

sexually active patients, large sample sizes and longer follow-up, are needed to confirm and expand on the findings of this study to provide further evidence to develop best practice in sexual rehabilitation.

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REFERENCES

1. Australian Institute of Health and Welfare. Australia's Health 2012. Available from: <https://strokefoundation.org.au/-/media/OD9E86AD13244763A9AAB35D9E389D.ashx?ia=en>.
2. Giaquinto S, Buzzelli S, Di Francesco L, Nolfi G. Evaluation of sexual changes after stroke. *J Clin Psychiatry* 2003; 64: 302–307.
3. Sjogren K, Fugl-Meyer AR. Sexual problems in hemiplegia. *Int Rehabil Med* 1981; 3: 26–31.
4. Tamam Y, Tamam L, Akil E, Yasan A, Tamam B. Post-stroke sexual functioning in first stroke patients. *Eur J Neurol* 2008; 15: 660–666.
5. Monga TN, Monga M, Raina MS, Hardjasudarma M. Hypersexuality in stroke. *Arch Phys Med Rehabil* 1986; 67: 415–417.
6. World Health Organization DoRHaR. Defining sexual health. Geneva: WHO; 2006.
7. National Stroke Foundation (Australia). Clinical guidelines for stroke management 2010. Available from: <http://strokefoundation.com.au/health-professionals/>.
8. von Linstow ME, Biering-Sørensen I, Liebach A, Lind M, Seitzberg A, Hansen RB, et al. Spina bifida and sexuality. *J Rehabil Med* 2014; 46: 891–897.
9. Kreuter MA, Taft CA, Siösteen AA, Biering-Sørensen FA. Women's sexual functioning and sex life after spinal cord injury. *Spinal Cord* 2011; 49: 154–160.
10. National Stroke Foundation (Australia). National Stroke Audit: Rehabilitation Services Report 2012. Available from: <https://strokefoundation.org.au/-/media/OD9E86AD13244763A9AAB35D9E389D.ashx?ia=en>.
11. Song H, Oh H, Kim H, Seo W. Effects of a sexual rehabilitation intervention program on stroke patients and their spouses. *NeuroRehabil* 2011; 28: 143–150.
12. Schmitz MA, Finkelstein M. Perspectives on poststroke sexual issues and rehabilitation needs. *Top Stroke Rehabil* 2010; 17: 204–213.
13. Stein J, Hillinger M, Clancy C, Bishop L. Sexuality after stroke: patient counseling preferences. *Disabil Rehabil* 2013. 35: 1842–1847.
14. Sansom J, Ng L, Zhang N, Khan F. Let's talk about sex: a pilot randomised controlled trial of a structured sexual rehabilitation programme in an Australian stroke cohort. *Int J Therap Rehabil* 2015; 22: 21–28.
15. National Stroke Foundation. Sex and relationships after stroke. 2013. Available from: <https://strokefoundation.org.au/-/media/OD9E86AD13244763A9AAB35D9E389D.ashx?ia=en>.
16. Annon JS. 8: The PLISSIT Model: A Proposed Conceptual Scheme for the Behavioral Treatment of Sexual Problems. *Gen Procedures* 1977: 70–83.
17. Keller A, McGarvey EL, Clayton AH. Reliability and construct validity of the Changes in Sexual Functioning

- Questionnaire short-form (CSFQ-14). *J Sex Marital Ther* 2006; 32: 43–52.
18. Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales*. Sydney: Psychology Found of Australia; 1995.
 19. Granger CV. The emerging science of functional assessment: our tool for outcomes analysis. *Arch Phys Med Rehabil* 1998; 79: 235–240.
 20. Hilari K, Lamping DL, Smith SC, Northcott S, Lamb A, Marshall J. Psychometric properties of the Stroke and Aphasia Quality of Life Scale (SAQOL-39) in a generic stroke population. *Clin Rehabil* 2009; 23: 544–557.
 21. Hilari K, Byng S, Lamping DL, Smith SC. Stroke and Aphasia Quality of Life Scale-39 (SAQOL-39): evaluation of acceptability, reliability, and validity. *Stroke* 2003; 34: 1944–1950.
 22. IBM SPSS Statistics for Windows. Version 21.0 ed. Armonk, NY: IBM Corp; Released 2012.
 23. Hayward KS, Barker RN, Carson RG, Brauer SG. The effect of altering a single component of a rehabilitation programme on the functional recovery of stroke patients: a systematic review and meta-analysis. *Clin Rehabil* 2014; 28: 107–117.
 24. Mückel S, Mehrholz J. Immediate effects of two attention strategies on trunk control on patients after stroke: a randomized controlled pilot trial. *Clin Rehabil* 2014; 28: 632–636.
 25. Hyde Z, Flicker L, Hankey GJ, Almeida OP, McCaul KA, Chubb SA, et al. Prevalence of sexual activity and associated factors in men aged 75 to 95 years: a cohort study. *Ann Int Med* 2010; 153: 693–702.
 26. Bretschneider JG, McCoy NL. Sexual interest and behavior in healthy 80- to 102-year-olds. *Arch Sexual Behavior* 1988; 17: 109.
 27. Helgason AR, Adolfsson J, Dickman P, Arver S, Fredrikson M, Gothberg M, et al. Sexual desire, erection, orgasm and ejaculatory functions and their importance to elderly Swedish men: a population-based study. *Age Ageing* 1996; 25: 285.
 28. Giraldi A, Rellini A, Pfaus JG, Bitzer J, Laan E, Jannini EA, et al. Questionnaires for assessment of female sexual dysfunction: a review and proposal for a standardized screener. *J Sexual Med* 2011; 8: 2681–2706.
 29. Klein R, Bar-on E, Klein J, Benbenishty R. The impact of sexual therapy on patients after cardiac events participating in a cardiac rehabilitation program. *Eu J Cardiovasc Prev Rehabil* 2007; 14: 672–678.
 30. Jette AM. The Post-Stroke Rehabilitation Outcomes Project. *Arch Phys Med Rehabil* 2005; 86: S1–S125.
 31. Gassaway J, Horn SD, DeJong G, Smout RJ, Clark C, James R. Applying the clinical practice improvement approach to stroke rehabilitation: methods used and baseline results. *Arch Phys Med Rehabil* 2005; 86: S16–S33.
 32. Horn SD, DeJong G, Smout RJ, Gassaway J, James R, Conroy B. Original article: Stroke rehabilitation patients, practice, and outcomes: is earlier and more aggressive therapy better? *Arch Phys Med Rehabil* 2005; 86: 101–114.