Appendix 4 Identifying Continence OptioNs after Stroke review: data abstraction form (version 2)

ICONS REVIEW: DATA ABSTRACTION FORM V2

RefMan ID		**Author & Year**	
Reviewer initials		**Title (first few words)**	

Reference multiple publications if used for data extraction	

Publication type

Published article	Book/book chapter	Thesis	Report	Abstract	Other (specify)

Study focus

RCT/quasi RCT				**Research study**		
combined behavioural	enhanced behavioural	method of delivery (to client)	method to implement (with staff)	develop, test or process evaluate intervention	subjective experiences of clients, carers, staff	correlating moderators with outcomes

FOR RCT/QUASI RCT OF COMBINED/ENHANCED BEHAVIOURAL UI INTERVENTIONS

RESEARCH AIM **(copy and paste from paper)**

RESEARCH DESIGN **(copy and paste from paper)**

Type of trial e.g. RCT, crossover	
Power calculation What outcome measure based on?	
Randomisation/ stratification description	
Total number randomised	

RESEARCH ARMS/NUMBERS:

Main intervention		**Comparison 1**		**Comparison 2**	
		Wait control, no treatment		Wait control, no treatment	
		Placebo/attention control		Placebo/attention control	
		Another treatment		Another treatment	
		a) drugs		a) drugs	
		b) physical therapy		b) physical therapy	
		c) surgery		c) surgery	
		d) other (specify)		d) other (specify)	
Notes:					

CLIENT GROUP

Recruitment/date of study

Clinical evaluation

Inclusion criteria	Exclusion criteria (copy and paste from paper)

Equivalence of groups results (copy and paste from paper)

Description		Category (tick)					
Ethnic groups (% white)							
Age range (mean, SD)		18-44		45-65		>65	
Sex (% female)		All female		All male		Mixed	
UI type (% Stress, % urge/OAB, % mixed		Stress		Mixed		Urge/ OAB	
Severity of incontinence (how assessed, criteria)		Moderate/severe		Mild		Mixed	
Symptom duration (mean, SD		1-2y		2-5y		>5y	
Cognitive incapacity (how assessed, criteria)		Excluded				Not excluded	
Diagnostic method		Urodynamic assessment				History only	
Equivalence check		Equivalence reported				Not reported	
Equivalence on UI parameters		Equivalent				Not equivalent	
Other criteria?							

Data relating to uptake/adherence		
	Rate	Factors affecting/reasons for failure (include source of data)
(Non) participation		
Treatment adherence		
Drop-out/follow up		
Long term sustainability		
Adverse effects		

INTERVENTION DETAILS

MAIN INTERVENTION CONTENT (copy and paste)

INTERVENTION DELIVERY (copy and paste)

CONTROL CONDITIONS (copy and paste)

PRE-INTERVENTION TREATMENT (copy and paste) e.g. treatment of infection

DEFINITION OF INCONTINENCE	TYPES OF INCONTINENCE	SEVERITY OF INCONTINENCE

MAIN INTERVENTION UI COMPONENTS

Category	Tick	Description/definition (copy/paste from paper)
BT		
PFMT		
PV		
Coping strategies for stress and urge UI to manage urgency/ detrusor instability e.g. the Knack, urethral clamping		
Techniques to facilitate bladder emptying e,g, urethral milking, toilet behaviour, muscle relaxation, double voiding		
Other UI strategy (specify)		

UI CORE INTERVENTION QUALITY

PFMT		BT		PV	
Confirm correct PFMC		Patient education			
Thorough individual instruction		Scheduled voiding			
Adherence check		Positive reinforcement			
Close follow up (i.e. every 2w)		Self monitoring/charting			
Longer training (i.e. 12 w or more)		Urge suppression techniques			

POTENTIAL CONFOUNDERS included in the INTERVENTION GROUP ONLY (after randomisation)

Category	Tick	Description/definition (copy/paste from paper)
Assessment		
Medication review (for UI related side effects)		
Treatment of infection		
Medication prescription (other)		
Referral to specialist		
Other		

INTERVENTION CONTEXT

Clients home	Acute care	Outpatient/ community clinic	Residential or subacute care	Other (specify)

CLIENT GROUP allocation to intervention

Intervention component	Who got this? - client subgroup
1.	
2.	
3.	

ADHERENCE STRATEGIES

Free text description (copy and paste from paper)				
Category		**Subcategories**		**Note**
INFORMATION PROVISION		General information on health		
		Information on consequences		
		Information on others approval		
		Provision of instruction		
		Model/demonstrate behaviour		
SELF-MONITORING				
ADHERENCE REMINDERS				
TAILORING/GOAL-SETTING		Prompt intention formation		
		Prompt barrier identification		
		Relapse prevention		
		Set graded tasks		
		Prompt specific goal setting		
		Prompt review of goals		
		Agree behavioural contract		
EXTERNAL MONITORING		Provide feedback		
EXTERNAL MOTIVATION/REINFORCEMENT		Provide general encouragement		
		Provide contingent rewards		
		Teach to use prompts or cues		
		Prompt practice		
		Use of follow up prompts		
COUNSELLING/COACHING		Prompt self talk		
		Prompt identification as role model		
		Plan social support/social change		
		Provide opportunity for comparison		
		Motivational interviewing		
		Stress management		
		Time management		
Other (describe)				

INTERVENTION THEORIES

Free text description (copy and paste)				
Health Education	**Social/cognitive learning**	**Social psychological**	**Behavioural**	**Muscle/exercise physiology**

INTERPRETATION OF INTERVENTION PURPOSE/LEVEL – what is the highest level this intervention could be interpreted as working at?

Classification	Tick	Justification
Increase knowledge		
Increase intention to practice		
Increase practice		
Increase consistency/quality of practice		
Increase effective/tailored practice		
Increase self-efficacy/independence		
Other (specify)		

DURATION/INTENSITY OF INTERVENTION

Number of exercises per day		Number of face to face sessions with HP		Number of other sessions with HP		Duration of programme in hours		Number of weeks program ran	
		1		1		<4		<4	
		2-4		2-4		4-12		4-12	
		>4		>4		>12		>12	
Notes if necessary:									

IF PFMT – METHOD OF PFMT TEACHING

Verbal instruction		Digital palpation		Biofeedback		EMG/ultrasound	
1		1		1		1	
2-4		2-4		2-4		2-4	
>4		>4		>4		>4	
Notes if necessary:							

OUTCOME DETAILS + TIMING

LOSS TO FOLLOW UP

	ALL	EXP	CONTROL
Number randomised			
Number lost, % loss			
Reason for losses			
Number at baseline			
Number at follow up 1			
Number lost, and % loss			
Reason for losses			
Number at follow up 2			
Number lost, and % loss			
Reason for losses			
Number at follow up 3			
Number lost, and % loss			
Reason for losses			
Number at follow up 4			

MEASUREMENT TOOLS + TIMING

			Data availability at time points				
	Scale/ instrument used	**Measure of:**	O = available but not in paper, X = in paper				
			Time 1	**Time 2**	**Time 3**	**Time 4**	**Time 5**
1							
2							
3							
4							
5							

DATA ANALYSIS

OUTCOME DATA EXTRACTION: REVIEW OF EFFECTIVENESS

What was measured?	Details of indicator/scale	Measurement tool	Experimental			Comparison 1			Comparison 2		
			n	Mean	SD	N	Mean	SD	n	Mean	SD
OBJECTIVE MEASURES											
Pad test											
Void timing, volume, retention											
SUBJECTIVE MEASURES											
Number of people regaining continence											
Number of incontinent episodes											
Perception of improvement or cure											
Subjective report of symptoms/severity											
Adherence											
Adverse effect											
Quality of life											
Carer outcome											
Socioeconomic measures											
Satisfaction with treatment											

ASSESSMENT OF STUDY QUALITY: RANDOMISED CONTROLLED TRIALS

Domain	Description	YES	UNCLEAR	NO	QUOTES AND COMMENTS
Sequence generation Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.		Was the allocation sequence adequately generated?			
Allocation concealment Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.		Was allocation adequately concealed?			
Blinding of participants, personnel and outcome assessors Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	*Assessments should be made for each main outcome (or class of outcomes).*	Was knowledge of the allocated intervention adequately prevented during the study?			NB Blinding of outcome assessors and analysis as standard
	Frequency of incontinent episodes:				
	Patient satisfaction/adverse events:				
Incomplete outcome data Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	*Assessments should be made for each main outcome (or class of outcomes).*	Were incomplete outcome data adequately addressed?			
	Frequency of incontinent episodes:				
	QOL				
Selective outcome reporting. State how the possibility of selective outcome reporting was examined by the review authors, and what was found.		Are reports of the study free of suggestion of selective outcome reporting?			
Other sources of bias. State any important concerns about bias not addressed in the other domains in the tool If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry					

OUTCOME DATA EXTRACTION: REVIEW OF BARRIERS/ENABLERS

Theme	Category	Data	TRANSFER

CATEGORISATION OF FINDINGS

CATEGORIES OF INFLUENCING FACTORS	INTERVENTION:	Choice/uptake	Participation/adherence	Longer term maintenance	Drop-out/ withdrawal	
CLIENT	BARRIERS					ENABLERS
INTERVENTION						
CONTEXT						

ASSESSMENT OF STUDY QUALITY: QUALITATIVE STUDIES

STANDARD	CRITERIA	YES	NO	Justification for decision
Appropriate research design	Justification for design/method discussed/appropriate			
Sampling	Clear explanation of how participants were selected			
	Appropriateness of sample to provide knowledge sought by study			
	Explanation of final sample and reasons for non-response			
Data collection	Clear explanation of what data were collected e.g. interview schedule, questions			
	Clear explanation of how data were collected/ methods are explicit, justified			
	Clear explanation of form of data, and modification during study, and data handling			
Analysis	In-depth description of analysis process			
	Clear description of how categories/themes were derived			
	Clear description of how data were selected /how contradictory data/ outliers were handled etc			
Findings	Sufficient explicit data presented to support findings			
	Adequate discussion of evidence for and against researchers arguments			
	Testing of robustness /credibility of findings			
Researcher reflexivity	Examination of own role, and potential for bias at all stages e.g. formulation, collection, analysis			
	Reflection of response to process, events, and relationship with respondents			
Generalisability	Can findings be applied to population of interest?			
Ethical issues	Any concerns about how research was explained to participants, informed consent, confidentiality			

ASSESSMENT OF STUDY QUALITY: OBSERVATIONAL STUDIES

STANDARD	CRITERIA	YES	NO	Justification for decision
Describes context	Describes the setting, location and relevant dates			
Sampling	Clear explanation of how participants were selected, i.e. gives eligibility criteria, source, method of selection			
	Appropriateness of sample to provide knowledge sought by study			
	Explanation of final sample and reasons for non-response			
Data collection	Clear explanation of what data were collected e.g. interview schedule, questions			
	Clear explanation of how data were collected/ methods are valid/reliable			
	Clear explanation of form of data, and modification during study, and data handling			
Analysis	Description of completeness of data/how missing data were handled			
	Type/method of analysis process adequately described			
Results	% response known for each section, number with missing data			
	Impact of bias/subgroups assessed			
	Reports numbers of events/outcomes			
Generalisability	Can findings be applied to population of interest?			
	Research was explained to participants, informed consent, confidentiality			

OUTCOME DATA EXTRACTION: PREDICTOR VARIABLES

	TIMING		OUTCOME =				
CODE	**VARIABLE CATEGORIES**		**Measured**	**Significant in UV analysis**	**Included in MV analysis**	**Independent predictor**	**Direction of correlation**
SOCIO-DEMOGRAPHIC VARIABLES							
SD-G	Sex						
SD-A	Age						
SD-R	Ethnicity						
SD-EI	Education/income						
PHYSIOLOGICAL UI VARIABLES							
P-P	Parity, menopause, hysterectomy						
P-W	Weight/BMI						
P-U	Urodynamic variables						
P-TR	Previous treatment						
P-D	Duration of UI						
P-TY	Type of UI						
P-S	Severity/degree of UI						
HEALTH/SELF-CARE VARIABLES							
H-G	General health/comorbidities						
H-SC	Self care/mobility						
H-C	Cognitive abilities						
PSYCHOLOGICAL VARIABLES							
PSY-HP	Health perceptions						
PSY-P	Psychological problems						
PSY-PSB	Perceptions of seriousness/benefits						
PSY-SEF	Self-efficacy						
PSY-CON	Perceptions of control						
PSY-COM	Compliance/adherence						
PSY-KT	Knowledge-correct technique						
PSY-MA	Motivation/attitude						
PSY-GA	Goal achievement						
PSY-SEM	Self esteem						
SOCIAL VARIABLES							
SOC-D	Social demands						
SOC-I	Social influences						

ASSESSMENT OF STUDY QUALITY: MULTIVARIATE ANALYSES OF PREDICTOR VARIABLE RELATIONSHIPS

STANDARD	CRITERIA	YES	NO	Justification for decision
Was a defined sample of patients assembled?	Participant selection – source and methods described			
Were appropriate confounding variables considered?	Reason for selection explained + type/severity of problem considered, where relevant to outcome			
Were objective and unbiased criteria used for measurement of predictors?	Predictor variables clearly defined with appropriate (e.g. diagnostic) criteria			
	Data sources/ measurement of predictors valid/reliable			
	Blinding of data collection for predictors			
Were objective and unbiased criteria used for measurement of outcome variables?	Outcome variables clearly defined with appropriate (e.g. diagnostic) criteria			
	Data sources/ measurement of outcomes valid/reliable			
	Blinding of data collection for outcomes			
Was the sample size adequate?	Were predictor variables present in a significant proportion of the population (rarity)?			
	Sample includes at least 10 cases* for each **PREDICTOR VARIABLE**** considered in MV analysis			
	Sample includes at least 10 cases* for each **PREDICTOR VARIABLE**** considered in UV analysis			
Was follow up sufficiently long/complete?	% follow up >80%			
	Reasons given for drop out			
Analysis appropriate	Statistical tests appropriate for data			
	Important confounders accounted for in design (e.g. matching, restricted randomisation) or analysis (adjustment/standardisation)			
	Precision of estimates (CIs or SEs) given			

* of lesser/last outcome category if outcome category is categorical
**counting categorical variables as 1 less predictors than its number of categories considered.

TABLE OF INCLUDED STUDIES

Aim		
Study details		
Country and participants	*Country*	
	Number of participants	
	Sample	
	Inclusion criteria	
	Exclusion criteria	
	Mean age	
	Type of incontinence	
Intervention	*Behavioural intervention*	
	Comparison group(s)	
Outcomes	*Primary outcome*	
	Secondary outcome(s)	
	Timing	
Notes	*Study quality*	
	Intervention quality	

AUTHOR CONTACT

Date	

NOTES

Source	

QUESTIONS

Source	