

Trial ID:

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

Resident's initials:

--	--

Completed by (initials):

--	--

Date completed:

--	--	--	--	--	--



electric tibial nerve stimulation  
to reduce incontinence in care homes

**ELECTRIC:**

**ELECtric Tibial nerve stimulation to Reduce  
Incontinence in Care homes**

**Baseline CRF**

To be completed by the Regional Research Assistant

Please return to Trial Office on completion

--	--	--	--	--

\_\_\_\_\_

## Contents

Contents.....	2
1. Baseline information.....	3
2. Functional ability - Barthel.....	8
3. Clinical Frailty Scale.....	11
4. Mini Mental State Examination .....	12
5. Falls, fractures, pressure ulcer risk/incidence .....	15
6. Outcome Measures.....	16
7. Resource use questionnaire.....	19
8. Patient Perception of Bladder Condition (P-PBC).....	20
9. Family/ Carer Perception of Bladder Condition (FC-PBC).....	21
10. Staff Perception of Bladder Control (S-PBC).....	22
11. Minnesota Toileting Skills Questionnaire – Resident (MTSQ-R).....	23
12. Minnesota Toileting Skills Questionnaire – Staff (MTSQ-S).....	24
13. DEMQOL – resident.....	25
14. DEMQOL PROXY– carer/staff.....	29
15. Randomisation .....	34
16. Baseline CRF Checklist.....	35

Some of this material has been reproduced with permission from: Talley K., Wyman J., Olson-Kellogg B., Bronas U., McCarthy T.(2016). Reliability and Validity of Two Measures of Toileting Skills in Frail Older Women Without Dementia. J Gerontol Nurs. 42(9) 16-20. doi: 10.3928/00989134-20160531-02

--	--	--	--	--

\_\_\_\_\_

## 1. Baseline information

### Continence history

PLEASE COMPLETE THE FOLLOWING USING INFORMATION GIVEN BY THE RESIDENT OR RESIDENT’S FAMILY OR RESIDENT CARE RECORDS /MEDICAL RECORDS/STAFF

1.1. Date of admission to care home

--	--	--	--	--	--

1.2. Continence assessment documented

Incontinence	Recorded – Y/N	Duration (years/months)/ not recorded
UI		
FI		
Both		

1.3. Is resident usually aware of need to pass urine?                      Y / N

1.4. Is resident usually aware of need to open bowels?                      Y / N

### Severity of UI

1.5. How often does the resident leak urine?    *(Please tick one box only)*

- Never
- About once a week or less often
- Two or three times a week
- About once a day
- Several times a day
- All the time

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

**1.6. How much urine is thought to usually be leaked (whether protection worn or not)?**  
(please tick one box only)

- None
- A small amount
- A moderate amount
- A large amount

**1.7. Overall, how much does leaking urine interfere with the resident's everyday life?**  
*Please circle a number between 0 (not at all) and 10 (a great deal)*

0    1    2    3    4    5    6    7    8    9    10

Not at all A great deal

**1.8. When does urine leak? (Please tick all that apply to the resident)**

- Never – urine does not leak
- Leaks before they can get to the toilet
- Leaks when they cough or sneeze
- Leaks when they are asleep
- Leaks when they are physically active/exercising
- Leaks when they have finished urinating and are dressed
- Leaks for no obvious reason
- Leaks all the time

Information provided by (please circle): resident / family member / staff / other – state:

\_\_\_\_\_

--	--	--	--	--

**1.9. What type of UI is the resident recorded as having?**

- Urgency UI
- Stress UI
- Mixed UI
- Functional UI
- Obstructive/overflow UI
- Type not recorded

**1.10. What bladder symptoms has the resident been recorded as having?**

- Urgency
- Frequency
- Nocturia
- Hesitancy
- Intermittency
- Post-micturition dribble
- Incomplete emptying
- Bladder pain
- Symptoms not recorded

**1.11. Is the resident recorded as having Benign Prostatic Hyperplasia (BPH)**

- Yes       No       N/A

--	--	--	--	--

\_\_\_\_\_

**Functional incontinence**

1.12. At this time, is the resident: **(Please tick all that apply)**

- Confined to bed
- Able to sit out but unable to stand unassisted
- Able to stand unassisted
- Mobile with assistance of ONE / TWO persons (please circle number)
- Mobile with assistance of equipment eg walking frame, wheelchair
- Independently mobile around home
- Mobile out of home independently

1.13. When the resident is trying to get to the toilet, are there any physical/cognitive restrictions which stop them getting there on time? **(Please tick all that apply)**

- Mobility
- Problems communicating their need to use the toilet
- Problems finding/locating toilet
- Does not try to get to the toilet
- Other

**IF OTHER, please explain below:**

\_\_\_\_\_

\_\_\_\_\_

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

**Management of current incontinence**

1.14. Does the resident wear pads continuously

Yes

No

1.15. Please record the total number and size of pads PRESCRIBED and WORN by the resident at night and during the day over a 24hr period:

	PRESCRIBED		WORN (from bladder diary)	
	Night-time	Day-time	Night-time	Day-time
Yes /No				
Number				
Type/brand				
Size				

1.16. Please tick which other methods of managing/treating incontinence the resident is recorded to have participated in: *(Please tick all that apply)*

- Toilet/voiding programme
- Fluid management- Describe: \_\_\_\_\_
- Drugs (inc patches)- State which drugs: \_\_\_\_\_
- Intermittent catheters
- Constipation management
- Bowel programme
- Other- Describe: \_\_\_\_\_

--	--	--	--	--

## 2. Functional ability - Barthel

**What is the resident's functional ability?**

**(For each question, please tick one box that is nearest the resident's ability)**

**2.1. Bathing: does the resident need any help to get in and out of the bath/shower?**

Need help

Independent

**2.2. Stairs: does the resident climb stairs?**

Unable to manage or have not tried stairs

With help

Independent

**2.3. Dressing: does the resident need any help with dressing?**

Dependent

Need help, can do about half

Independent (includes buttons, zips, laces)

**2.4. Mobility: does the resident need any help to walk about indoors?**

Immobile

Can get about in wheelchair

Need help/supervision of 1 person

Independent



--	--	--	--	--

**2.5. Transfers: does the resident need any help to get in and out of bed?**

- Unable to sit out of bed
- Need help of 2 people but can sit out
- Need help/supervision of 1 person
- Independent

**2.6. Feeding: does the resident need any help with feeding or cutting up their food?**

- Dependent
- Need some help, e.g. cutting
- Independent in all actions

**2.7. Toilet: does the resident need any help in the toilet (getting on or off, dealing with clothes)?**

- Dependent
- Need some help
- Independent in all actions

**2.8. Grooming: does the resident need any help with brushing teeth, combing hair, or (men only) shaving?**

- Needs help
- Independent for face/hair/teeth/shaving

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

**2.9. Urinary function: does the resident have any problems controlling their bladder?**

- Incontinent (or catheter)
- Occasional accident
- Fully continent (no accidents)

**2.10. Bowel function: does the resident have any problems controlling their bowels?**

- Incontinent (or cannot go without enemas)
- Occasional accident
- Fully continent (no accidents)

Information provided by (please circle): resident / family member / staff / other – state:

\_\_\_\_\_

--	--	--	--	--

### 3. Clinical Frailty Scale

Consider the description of the 9 frailty categories below, and circle ONE of the images that best describes the resident

#### Clinical Frailty Scale\*



**1 Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



**2 Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



**3 Managing Well** – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



**4 Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being "slowed up", and/or being tired during the day.



**5 Mildly Frail** – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



**6 Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



**7 Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



**8 Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



**9. Terminally Ill** - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

#### Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

\* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

© 2007-2009. Version 1.2. All rights reserved. Geriatric Medicine Research, Dalhousie University, Halifax, Canada. Permission granted to copy for research and educational purposes only.

--	--	--	--	--

\_\_\_\_\_

## 4. Mini Mental State Examination

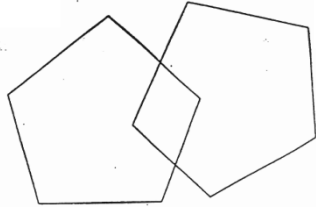
4.1. Say: "I am going to ask you some questions and give you some problems to solve. Please try to answer as best you can."

Allow ten seconds for each reply. Score one point for each correct response within each question or activity.

		Max score	Resident score
i. Orientation to time	Can you tell me?		
	What is today's date?	1	
	What is today's month?	1	
	What is the year?	1	
	What is the day of the week today?	1	
	What season is it?	1	
ii. Orientation to place	Can you tell me?		
	Whose home is this?	1	
	What room is this?	1	
	What city /town are we in?	1	
	What is the county?	1	
	What is the country ?	1	
iii. Immediate recall	I should like to test your memory. (name 3 common objects: e.g. "ball, car, man") Can you repeat the words I said (score 1 point for each word) (repeat up to 6 trials until all three are remembered) record number of trials needed here: <input type="text"/>		
	Ball	1	
	Car	1	
	Man	1	
iv. Attention and Calculation	a) From 100 keep subtracting 7 and give each answer: Alternatively b) Spell the word 'WORLD' backwards, (D - L - R - O - W).		
	93	D	1
	86	L	1
	79	R	1
	72	O	1
	65	W	1
v. Recall	What were the three words I asked you to say earlier? (Skip this test if all three objects were not remembered during registration test).		
	Ball	1	
	Car	1	
	Man	1	

--	--	--	--	--

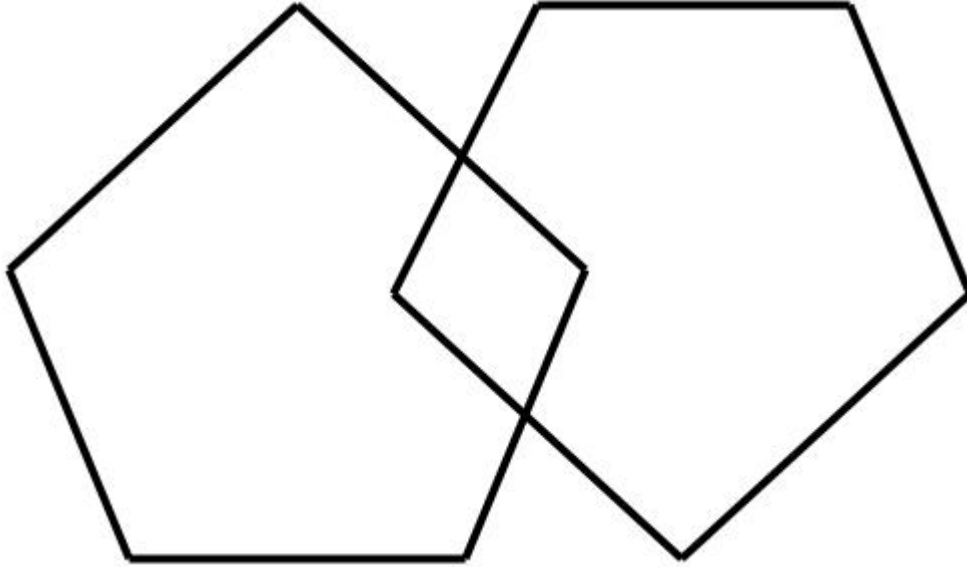
\_\_\_\_\_

vi. Language - Naming	Name these objects (show a watch) (show a pen)		
	Watch	1	
	Pen	1	
vii. Repeating	Repeat the following: "no ifs, and or buts"		
		1	
viii. Reading	(show card or write "CLOSE YOUR EYES") Say: 'Read this sentence and do what is says'		
	Score 1 if they close their eyes	1	
ix. Writing	Ask resident to write a sentence Say: 'Now can you write a short sentence for me?'		
	If sentence contains a subject and a verb, and is sensible, give the point. Ignore mistakes such as grammar or punctuation	1	
x. Language – 3 stage command	(Present paper) Say – 'Take this paper in your left (or right) hand, fold it in half and put in on the floor'		
	Resident takes paper	1	
	Folds paper in half	1	
	Puts paper on floor	1	
xi. Copying	Show drawing and ask resident to copy (give paper and pen)		
	If 10 angles present and 2 intersect, give point. Ignore tremor and rotation	1	
			

NB Please see over for larger image of above diagram

--	--	--	--	--

\_\_\_\_\_



Please copy the drawing in the space below

--	--	--	--	--

\_\_\_\_\_

## 5. Falls, fractures, pressure ulcer risk/incidence

### 5.1. Record the following from the resident's care home/medical records:

In previous 6 months	Number	Comments
i. Recorded falls		
ii. Injurious falls		
iii. Recorded fracture(s)		
iv. Site(s) of recorded fracture(s) eg neck of femur, humerus		
v. Recorded UTIs treated with antibiotics		
vi. Admissions or unplanned visits to A&E/hospital		
vii. Urology /urogyneacology/continence service appointments (may be in care home)		
viii. Pressure ulcers recorded in past month		
ix. Site(s) of recorded pressure ulcer(s)		
x. Non-pressure wounds recorded in past month		
Pressure ulcer risk score in past month:		
xi. Braden score		
xii. Waterlow score		
xiii. Norton score		
xiv. Other pressure ulcer risk assessment score: Name.....		

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

## 6. Outcome Measures

Please record the following outcome measures from information provided on the bladder diary and data from the 24 hour pad weigh.

6.1. Use the 24 hour bladder diary to record the following:

	Number	Comments (from bladder diary)
Visits to toilet - 24 hours (1 day)		
Voids in toilet - 24 hours (1 day)		
Pads used – 24 hours(1 day)		
Soiled pads included - 24 hour (1 day) collection		

6.2. Record the dry pad weight based on the number and size of pads used during the 24 hour pad collection period & ENTER ONTO THE TRIAL DATABASE

Size & make of pad used (use separate row for each size used)	Number	Dry weight in grams (weigh a dry, unused pad of same make/size)

6.3. Record the total wet pad weight of pads collected in the 24hr pad collection (weigh bag containing all pads) & ENTER ONTO THE TRIAL DATABASE

Total weight:

_____g
--------



--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

Once dry and wet pad weights are entered onto the trial database, the database will calculate the volume of urine leaked and level of incontinence (Q6.4 and Q6.5). Please record the results given on the database in the box below:

**6.4 Calculate the volume of urine leaked during 24 hour pad collection:**

(Minus)

**Total wet pad weight - Total dry pad weight = Total volume of urine leaked**

\_\_\_\_\_g - \_\_\_\_\_g = \_\_\_\_\_g

**6.5 Level of urinary incontinence (tick one based on 24 pad weight test calculation)**

Mild (0-200ml/24hr)

Moderate (200-400ml/24hr)

Severe (400+ml/24hr)

**6.6 Please record three measurements of Post Void Residual Urine Volume (PVRU) obtained. Take all measurements at the same time i.e. after the resident has voided:**

1<sup>st</sup> measurement \_\_\_\_\_ ml

2<sup>nd</sup> measurement \_\_\_\_\_ ml

3<sup>rd</sup> measurement \_\_\_\_\_ ml

Date PVRU measurements complete

--	--	--	--	--	--

**6.7 Use the 3 measurements in 6.6 to calculate the average PVRU (divide the total of all measurements by 3):**

Average PVRU: \_\_\_\_\_ ml

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

**6.8 If average PVRU >300ml as calculated in 6.7 repeat measurements the following day or ASAP and record below:**

**1<sup>st</sup> measurement** \_\_\_\_\_ ml

**2<sup>nd</sup> measurement** \_\_\_\_\_ ml

**3<sup>rd</sup> measurement** \_\_\_\_\_ ml

**Date repeat PVRU measurements complete**

--	--	--	--	--	--

**6.9 Use the 3 measurements in 6.8 to calculate the average PVRU (divide the total of all measurements by 3):**

**Average PVRU:** \_\_\_\_\_ ml

--	--	--	--	--

\_\_\_\_\_

## 7 Resource use questionnaire

### 7.1 Medication prescribed for incontinence (including for BPH in men)

Name of medication (generic name preferred)	Dose per day	Ongoing medication? (Y/N)	If No, indicate how many days medication prescribed

7.2 Is assistance required from care home staff to attend toilet? Yes /No \_\_\_\_\_

i. If yes, please indicate how many staff are required per visit : \_\_\_\_\_

ii. If yes, please indicate how many visits (on average) are required per day (see bladder diary) : \_\_\_\_\_

7.3 Has any special equipment been provided as a result of participant incontinence (eg. Sheets, hoists, commode) DO NOT INCLUDE ABSORBENT PADS

Item	Used on a daily basis?

--	--	--	--	--

## 8 Patient Perception of Bladder Condition (P-PBC)

**IF THE RESIDENT HAS CAPACITY/LUCID MOMENTS, ASK THEM THE FOLLOWING QUESTION AND RECORD THEIR ANSWER. IF THEY DON'T HAVE CAPACITY TO ANSWER THIS QUESTION RECORD IN TOP RIGHT CORNER OF THIS PAGE**

### 8.1 Which of the following statements describes your bladder condition best at the moment?

Please mark "X" in one box only.

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder condition causes me some minor problems.
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

--	--	--	--	--

\_\_\_\_\_

## 9 Family/ Carer Perception of Bladder Condition (FC-PBC)

**FOR ALL RESIDENTS PLEASE ASK A FAMILY MEMBER OR REGULAR VISITOR OF THE RESIDENT WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW. Where possible this will be the same person for all time points.**

**9.1 Which of the following statements do you think best describes your relative/friend's bladder condition at the moment? Please mark "X" in one box only.**

- Their bladder condition does not cause them any problems at all.
- Their bladder condition causes them some very minor problems.
- Their bladder condition causes them some minor problems.
- Their bladder condition causes them (some) moderate problems.
- Their bladder condition causes them severe problems.
- Their bladder condition causes them many severe problems.
  
- Relative / carer not aware of bladder condition
- Relative / carer not willing to answer 9.1 (perception of bladder condition)

**9.2 Name of person answering question 9.1: \_\_\_\_\_**  
**and relationship to resident \_\_\_\_\_**

--	--	--	--	--

## 10 Staff Perception of Bladder Control (S-PBC)

**FOR ALL RESIDENTS PLEASE ASK A MEMBER OF STAFF INVOLVED IN THEIR CARE WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW. Where possible this will be the same staff member for each time point.**

**10.1 Which of the following statements do you think best describes the resident's bladder condition at the moment? Please mark "X" in one box only.**

- Their bladder condition does not cause them any problems at all.
- Their bladder condition causes them some very minor problems.
- Their bladder condition causes them some minor problems.
- Their bladder condition causes them (some) moderate problems.
- Their bladder condition causes them severe problems.
- Their bladder condition causes them many severe problems.

**10.2 Name & role of person answering question 10.1:**

\_\_\_\_\_

\_\_\_\_\_

--	--	--	--	--

If section not complete state reason: \_\_\_\_\_

\_\_\_\_\_

## 11 Minnesota Toileting Skills Questionnaire – Resident (MTSQ-R)

**IF THE RESIDENT HAS CAPACITY/LUCID MOMENTS, ASK THEM THE FOLLOWING QUESTION AND RECORD THEIR ANSWER. IF THEY DON'T HAVE CAPACITY TO ANSWER THIS QUESTION RECORD IN TOP RIGHT CORNER OF THIS PAGE**

**11.1 Please consider each of the five scenarios in the table below and rate how difficult you find them to do using the following scale:**

**Response options: 0 = none, 1 = a little, 2= some, 3= quite a lot, and 4 = cannot do**

<b>How much difficulty do you have...</b>	<b>Response (0-4)</b>
putting on and taking off long trousers (including managing fasteners)?	
walking through your home to get to the toilet in time?	
sitting down on and standing up from the toilet?	
reaching to the side to grab toilet paper?	
reaching your bottom to wipe with toilet paper?	

--	--	--	--	--

\_\_\_\_\_

## 12 Minnesota Toileting Skills Questionnaire – Staff (MTSQ-S)

**FOR ALL RESIDENTS PLEASE ASK A MEMBER OF STAFF INVOLVED IN THEIR CARE WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW. Where possible this will be the same staff member for each time point.**

**12.1 Please consider each of the five scenarios in the table below and rate how difficult you think the resident finds them to do using the following scale:**

**Response options: 0 = none, 1 = a little, 2= some, 3= quite a lot, and 4 = cannot do**

How much difficulty do they have...	Response (0-4)
putting on and taking off long trousers (including managing fasteners)?	
walking through the home to get to the toilet in time?	
sitting down on and standing up from the toilet?	
reaching to the side to grab toilet paper?	
reaching their bottom to wipe with toilet paper?	

**12.2 Name & role of person answering question 12.1:** \_\_\_\_\_

\_\_\_\_\_



--	--	--	--	--

\_\_\_\_\_

## 13 DEMQOL – resident

**IF THE RESIDENT HAS CAPACITY/LUCID MOMENTS, ASK THEM THE FOLLOWING QUESTIONS AND RECORD THEIR ANSWERS. IF THEY DON'T HAVE CAPACITY TO ANSWER THESE QUESTIONS RECORD IN TOP RIGHT CORNER OF THIS PAGE.**

Read each of the following questions (in bold) verbatim and show the respondent the response card.

Say ***“I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody. Before we start we'll do a practise question; that's one that doesn't count.”*** (Show the response card and ask respondent to say or point to the answer) ***“In the last week, how much have you enjoyed watching television?”***

a lot

quite a bit

a little

not at all

Follow up with a prompt question: **Why is that? or Tell me a bit more about that.**

--	--	--	--	--

For all of the questions I'm going to ask you, I want you to think about the last week.

13.1 First I'm going to ask about your feelings. In the last week, have you felt.....

	A lot	Quite a bit	A little	Not at all
i. cheerful?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. that you are enjoying life?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. confident?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. full of energy?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. lonely?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. lively?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xii. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xiii. that there are things that you wanted to do but couldn't?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

--	--	--	--	--

**13.2 Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....**

	A lot	Quite a bit	A little	Not at all
i. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. forgetting who people are?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. your thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. poor concentration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**13.3 Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about.....**

	A lot	Quite a bit	A little	Not at all
i. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. how you get on with people close to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. getting the affection that you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. people not listening to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. making yourself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. getting help when you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. getting to the toilet in time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. how you feel in yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. your overall health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

--	--	--	--	--

\_\_\_\_\_

**13.4 We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate.....**

**i. your quality of life overall?**      **Very good**      **Good**      **Fair**      **Poor**  
                 

\*\* items that need to be reversed before scoring

© Institute of Psychiatry, King's College London

--	--	--	--	--

\_\_\_\_\_

## 14 DEMQOL PROXY- carer/staff

**FOR ALL RESIDENTS PLEASE ASK A FAMILY MEMBER OR MEMBER OF STAFF INVOLVED IN THEIR CARE WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTIONS AND RECORD THEIR ANSWERS BELOW. Where possible this will be the same family member/staff member for each timepoint.**

Read each of the following questions (in bold) verbatim and show the respondent the response card.

Say **"I would like to ask you about \_\_\_\_\_ (your relative's) life, as you are the person who knows him/her best. There are no right or wrong answers. Just give the answer that best describes how \_\_\_\_\_ (your relative) has felt in the last week. If possible try and give the answer that you think \_\_\_\_\_ (your relative) would give. Don't worry if some questions appear not to apply to \_\_\_\_\_ (your relative). We have to ask the same questions of everybody. Before we start we'll do a practise question; that's one that doesn't count."** (Show the response card and ask respondent to say or point to the answer). **"In the last week how much has \_\_\_\_\_ (your relative) enjoyed watching television?"**

a lot

quite a bit

a little

not at all

Follow up with a prompt question: **Why is that?** or **Tell me a bit more about that.**

**14.1 What is the name of the proxy answering questions for the DEMQOL**

Proxy? \_\_\_\_\_

**14.2 What is the relationship of the person named in 14.1 to the**

resident? \_\_\_\_\_

--	--	--	--	--

For all of the questions I'm going to ask you, I want you to think about the last week.

14.3 First I'm going to ask you about \_\_\_\_\_ (*your relative's*) feelings. In the last week, would you say that \_\_\_\_\_ (*your relative*) has felt .

	A lot	Quite a bit	A little	Not at all
i. cheerful? **	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. full of energy? **	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. content? **	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. lively? **	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. that he/she has things to look forward to? **	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

--	--	--	--	--

14.4 Next, I'm going to ask you about \_\_\_\_\_ (*your relative's*) memory. In the last week, how worried would you say \_\_\_\_\_ (*your relative*) has been about.

	A lot	Quite a bit	A little	Not at all
i. his/her memory in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. forgetting things that happened a long time ago?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. forgetting people's names?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. forgetting where he/she is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. his/her thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. making him/herself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

--	--	--	--	--

14.5 Now, I'm going to ask about \_\_\_\_\_ (*your relative's*) everyday life. In the last week, how worried would you say \_\_\_\_\_ (*your relative*) has been about.

	A lot	Quite a bit	A little	Not at all
i. keeping him/herself clean (eg washing and bathing)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. keeping him/herself looking nice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. getting what he/she wants from the shops?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. using money to pay for things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. looking after his/her finances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. things taking longer than they used to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. getting in touch with people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. not being able to help other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. not playing a useful part in things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. his/her physical health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



--	--	--	--	--

14.6 We've already talked about lots of things: \_\_\_\_\_ (*your relative's*) feelings, memory and everyday life. Thinking about all of these things in the last week, how would you say \_\_\_\_\_ (*your relative*) would rate:

i. his/her quality of life overall?      Very good      Good      Fair      Poor

--	--	--	--	--

\_\_\_\_\_

## 15 Randomisation

Now that the baseline CRF has been completed, please ensure all data required for randomisation of this participant have been entered onto the trial database:

15.1 **What is the sex of the participant? (circle)** **Male /Female**

Sex of participant entered onto database? (tick)

15.2 **What level of urinary incontinence does the participant have? (circle)**

Take this information from the answer to Q6.5 calculated by the database when you entered the dry and wet pad weights.

**Mild**

**Moderate**

**Severe**

Level of incontinence entered onto database? (tick)

15.3 **Record date all information for randomisation entered onto database:**

--	--	--	--	--	--

--	--	--	--	--

\_\_\_\_\_

## 16 Baseline CRF Checklist

Please tick the boxes below to confirm that you have completed and entered all the required data for this CRF before returning it to the trial office. If any section is not completed, please indicate why using the space on the top right hand corner of each page:

1. Continence history and current treatment
2. Barthel Index (functional ability)
3. Clinical Frailty Scale
4. Mini Mental State Examination
5. Falls, fractures & pressure ulcer record
6. Number of pads from 24hr pad collection 
  - Weight of 24hr used pad collection
  - 3 measurements of PVRU
7. Resource use questionnaire
8. PPBC
9. FCPBC
10. SPBC
11. MTSQ-R
12. MTSQ-S
13. DEMQOL
14. DEMQOL Proxy
15. Participant randomised?