CLIENT SERVICE RECEIPT INVENTORY

☐ Baseline
☐ 12 Weeks
☐ 24 Weeks
☐ 52 Weeks
☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | |

SECTION A. STUDY PARTICIPANT

1. How many people are there in the participant's household?

	Number
Number of adults including study participant	
Number of children under the age of 16 years	

2. What kind of accommodation does the participant live in at the moment? *(tick **one** box)*

1. Council-rented housing ☐
2. Housing-association rented housing ☐
3. Private rented housing ☐
4. Owner-occupied housing ☐
5. Other housing (please describe in box) ☐

3. Is the participant's accommodation "sheltered" housing (has a warden or scheme manager on-site)?

1. Yes ☐
2. No ☐

4. Has the participant lived anywhere else during <u>the last 3 months</u> (excluding hospital stays)?

1. Yes ☐ → ***Go to Q5***
2. No ☐ → ***Go to Q6***

5. What type of accommodation did the participant stay in at that time?

If participant reports a stay in a care/nursing home or other location, complete the questions in that row.

Service	No	Yes	Reason for using service (e.g. respite)	Name of home (not to be entered into database)	Number of days	Participant or family contribution		Provider (*see note**)
						No	Yes	
Residential care home	☐	☐			☐☐	☐	☐	☐
Nursing home	☐	☐			☐☐	☐	☐	☐
Other - please describe using 'Name of home' box	☐	☐			☐☐	☐	☐	☐

*[*Note: Use the "Name of home" information to complete the Provider box, using provider codes, after the interview]*

Provider codes

1	Local authority/Social Services/Council
2	NHS
3	Voluntary/charitable organisation
4	Private company or insurance company
5	Self or family members
6	Other
7	Researcher unable to classify response
8	Not completed

Community health and social services

6. In the <u>last 3 months</u>, has the study participant used any of the services below?

[SHOW CARD 1]

Service	No	Yes	No. of home visits	No. clinic or office visits	Average duration of contact (minutes)
GP	☐	☐	☐☐	☐☐	☐☐☐
Practice nurse (at GP surgery)	☐	☐	☐☐	☐☐	☐☐☐
Community/District Nurse	☐	☐	☐☐	☐☐	☐☐☐
Community psychiatric / Community Mental Health Nurse	☐	☐	☐☐	☐☐	☐☐☐
Psychiatrist	☐	☐	☐☐	☐☐	☐☐☐
Social worker or care manager	☐	☐	☐☐	☐☐	☐☐☐
Psychologist	☐	☐	☐☐	☐☐	☐☐☐
Physiotherapist	☐	☐	☐☐	☐☐	☐☐☐
Occupational therapist	☐	☐	☐☐	☐☐	☐☐☐
Dietician	☐	☐	☐☐	☐☐	☐☐☐
Paramedic (See and Treat only)	☐	☐	☐☐	☐☐	☐☐☐
Mental health team worker	☐	☐	☐☐	☐☐	☐☐☐
Specialist nurse (e.g. Admiral Nurse, palliative care nurse, respiratory nurse) - *please describe in box*	☐	☐	☐☐	☐☐	☐☐☐

☐

7. In the <u>last 3 months</u>, has the participant used any of the services below?

[SHOW CARD 2]

Note: please tick the 'no' box if participant has not used the service

Service	No	Yes	Number of home visits	No. of clinic / office visits	Average duration of contact (minutes)	Participant or family contribution	
						No	Yes
Home care/home help Name:_____	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Home care/home help: additional organisation Name:_____	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Home care/home help: additional organisation Name:_____	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Cleaner	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Meals on wheels	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Laundry service	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Sitting service (e.g. Crossroads)	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Carer's support worker	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Optician	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Chiropodist	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Dentist	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
Other health or social care services:							
1. ……	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐
2. ……	☐	☐	☐☐☐	☐☐	☐☐☐	☐	☐

Day services

8. In the <u>last 3 months</u> has the participant used any of the day services below?

[SHOW CARD 3] *Note: please tick the 'no' box if participant has not used the service*

For 'Participant or family contribution', ask: 'Did you or a family member pay for this service?'

Service	No	Yes	Number of times per week	Number of times in last 3 months	Name of service (not to be entered into database)	Did participant or family pay or contribute		Provider (*see note**)
						No	Yes	
Day centre	☐	☐	☐☐	☐☐☐		☐	☐	☐
Lunch club	☐	☐	☐☐	☐☐☐		☐	☐	☐
Patient education group (e.g. reminiscence) *please describe:* ……	☐	☐	☐☐	☐☐☐		☐	☐	☐
Other health or social care day services:								
1. ……	☐	☐	☐☐	☐☐☐		☐	☐	☐
2. ……	☐	☐	☐☐	☐☐☐		☐	☐	☐

*[*Note: Use the "Name of service" information to complete the Provider box, using provider codes, after the interview*

Provider codes

1	Local authority/Social Services/Council
2	NHS
3	Voluntary/charitable organisation
4	Private company or insurance company
5	Self or family members
6	Other
7	Researcher unable to classify response
8	Not completed

Hospital services

9. <u>In the last 3 months</u> has the participant used any of the following hospital services?

Note: please tick the 'no' box if participant has not used the service

For 'Reason for using service', A&E, ask also: whether participant arrived at A&E by ambulance

Service	No	Yes	Name of ward, clinic hospital or centre	Reason for using service (condition, specialty)	Unit of measurement	No. of days/ attended
Accident & Emergency Department (A&E)	☐	☐			Attendance	☐ ☐
Inpatient ward admission 1	☐	☐			Inpatient day	☐ ☐
Inpatient ward admission 2	☐	☐			Inpatient day	☐ ☐
Inpatient ward admission 3	☐	☐			Inpatient day	☐ ☐
Inpatient ward admission 4	☐	☐			Inpatient day	☐ ☐
Inpatient ward admissions 5	☐	☐			Inpatient day	☐ ☐
Outpatient Department (OPD) Attendance 1	☐	☐			Appointment	☐ ☐
OPD Attendance 2	☐	☐			Appointment	☐ ☐
OPD Attendance 3	☐	☐			Appointment	☐ ☐
OPD Attendance 4	☐	☐			Appointment	☐ ☐
OPD Attendance 5	☐	☐			Appointment	☐ ☐
Day hospital Attendance 1	☐	☐			Day attendance	☐ ☐
Day hospital Attendance 2	☐	☐			Day attendance	☐ ☐

Equipment and adaptations

10. <u>In the last 3 months</u> has the participant had any adaptations or equipment for his/her condition? [SHOW CARD 4]

1. **Yes** ☐
2. **No** ☐

If yes, *for each type of change or equipment that the participant has had code,"1" for yes and "0" for no and ask '*who or which organisation paid for these'*. Tick as many organisations as apply.*

		Who/Which organisation paid or this?				
Type of adaptation or equipment	**Code**	**Council**	**NHS**	**Self**	**Volunt/ charity**	**Other**
Outdoor railing	☐	☐	☐	☐	☐	☐
Grab rail/Stair rail	☐	☐	☐	☐	☐	☐
Walking stick	☐	☐	☐	☐	☐	☐
Walking frame	☐	☐	☐	☐	☐	☐
Walk-in shower/shower cubicle replacing bath	☐	☐	☐	☐	☐	☐
Over-bath shower	☐	☐	☐	☐	☐	☐
Bath seat/shower seat	☐	☐	☐	☐	☐	☐
Kitchen stool	☐	☐	☐	☐	☐	☐
Bed lever/rail	☐	☐	☐	☐	☐	☐
Toilet frame/raised toilet seat	☐	☐	☐	☐	☐	☐
Commode	☐	☐	☐	☐	☐	☐
Continence pads	☐	☐	☐	☐	☐	☐

11. <u>In the last 3 months</u> has the participant had any other adaptations or equipment for his/her condition? Please describe.

		Who/which organisation paid for this?				
Type of adaptation or equipment	**Tick if yes**	**Council**	**NHS**	**Self**	**Volunt./ charity**	**Other**
1._____	☐	☐	☐	☐	☐	☐
2. _____	☐	☐	☐	☐	☐	☐

Medications

12. Has the participant taken any medications for his/her condition over the last 3 months?

Tradename	First day	Last day (if applies)	Ongoing (if applies)	Dose	Medication unit code	Frequency code
DEMENTIA DRUGS	dd/mm/yy	dd/mm/yy				
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
OTHER MENTAL HEALTH DRUGS						
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐
_____	__/__/__	__/__/__	☐	☐☐☐	☐☐	☐☐

Tick if participant does not take any medications for his/her condition ☐

Medication unit codes

1	Mg	7	Drops
2	microgram	8	Sprays (spray)
3	Gram	9	Bottles
4	Ml	10	Packs
5	Tubs/tubes	11	IU (injections)
6	Puffs (inhalers)	99	Other – give details

Medication frequency codes

1	Once daily	7	Once a week
2	Twice daily	8	Once every two weeks
3	Three times daily	9	Once every three weeks
4	Four times daily	10	Once every four weeks
5	Three times a week	11	Once every five weeks
6	Twice a week	88	As required / “PRN”

SECTION B. SUPPORT PROVIDED BY UNPAID CARERS

1. Do you live with the study participant?

1. **Yes** ☐ → *Go to Q5*

2. **No** ☐ → *Go to Q2*

2. How many people are there in your household?

	Number
Number of adults (including respondent)	☐☐
Number of children under the age of 16 years	☐☐

3. What kind of accommodation do you live in at the moment? *(tick **one** box)*

1. Council-rented housing ☐
2. Housing-association rented housing ☐
3. Private rented housing ☐
4. Owner-occupied housing ☐
5. Other housing (please describe in box) ☐ ☐

4. Is your accommodation "sheltered" housing (has a warden or scheme manager on-site)?

1. **Yes** ☐

2. **No** ☐

Employment

5. Which of the following best describes your current employment situation?
(*Tick the one box that applies best to carer's situation*)

- In paid employment → ***GO TO Q6***
- Retired → ***GO TO Q8***
- Unable to work → ***GO TO Q8***
- Unemployed and looking for work → ***GO TO Q8***
- At home and not looking for work (e.g. housewife/husband) → ***GO TO Q8***
- Doing voluntary work → ***GO TO Q8***
- Student (full or part-time) → ***GO TO Q8***
- Other (Please describe) → ***GO TO Q8***

If carer is employed:

6. What is your current job(s)/occupation(s)?

7. Number of hours you work per week in all the jobs you do ☐☐

If carer is unemployed, unable to work, 'at home' or retired:

8. When were you last employed? (Month/Year)

☐☐ mm ☐☐ y y

9. What was/were your most recent job(s)/occupation(s)?

10. Have you given up or cut down on work in order to provide care for the study participant?

- Yes, given up work → ***GO TO Q11***
- Yes, cut down → ***GO TO Q11***
- No → ***GO TO Q13***

If carer gave up or cut down work*:*

11. When did this happen? (Month/Year)

☐☐ mm ☐☐ yy

If carer cut down on work:

12. By how much did you cut down on work each week? ☐☐ Hours per week

13. In an average week, what tasks do you help the study participant with? (*Tick as many as apply*)

Personal care	☐
Helping with finances	☐
Practical help (housework, laundry)	☐
Taking the person out (to appointments, social visits)	☐
Medications	☐
Making sure the person is safe (supervision)	☐
Other, describe:	☐

14. In an average week, how much time do you spend looking after/providing help for the study participant with these types of tasks? (*Tick the one box that applies best*)

No help in the last week	☐
Less than one hour	☐
1-4 hours	☐
5-8 hours	☐
9-14 hours	☐
15-22 hours	☐
23-30 hours	☐
31-49 hours	☐
50-99 hours	☐
100 hours or more	☐
Other, describe:	☐

Other carers

15. **Other than yourself, do other friends or relatives regularly help/provide care for your relative**?

1. Yes ☐ → ***GO TO Q16***

2. No ☐ → ***GO TO Q20***

16. **Thinking about an average week, how many such carers help/provide care for the study participant?**

☐☐

17. **Thinking about an average week, and about <u>all</u> such carers, for how many hours do they help/provide care for the study participant?**

Hours per week ☐☐☐

18. **Have any friends and relatives taken time off paid work over the last 3 months to help/provide care for the your relative?**

1. Yes ☐

2. No ☐

19. **If yes, can you estimate the <u>total</u> number of days that relatives or friends have taken off work over the last 3 months to help/provide care for the study participant?**
(If no, write 0 in boxes)

Total days ☐☐☐

Travel Costs

20. In the last 3 months, have you accompanied the study participant to any clinic, GP, hospital, or day services for his/her condition?

1. Yes	☐ →	***GO TO Q21***
2. No	☐ →	***NO FURTHER QUESTIONS***

21. If yes, over the last 3 months, how many times did you accompany the study participant?

	Number of times per week	**Number of times in last 3 months**
Accompanied respondent	☐☐	☐☐

22. How did you normally travel to get to the services the study participant used (*e.g. to go any clinic, GP surgery, hospital or day services for his/her condition)***? If you used more than one form of transport please say how you travelled for the main/longest part of your journey.**

☐ [use TRANSPORT code]

TRANSPORT codes

1	Walked	6	Drove the car
2	Cycled	7	Took hospital transport
3	Took the bus	8	Went by ambulance
4	Took the train	9	Other
5	Took a taxi		

23. How long did it normally take to travel there from home?

	Hours	Minutes
Number of	☐☐	☐☐

24. If you normally travelled by public transport, what was the cost of the fare in one direction?

	£	pence
Cost of one-way fare	☐☐	☐☐

25. If you normally travelled by taxi, what was the cost of the fare in one direction?

	£	pence
Cost of one-way fare	☐☐	☐☐

26. If you normally travelled by car, how many miles/kilometres did you travel to get there? *(write in underlined space whether using miles or kilometres)*

Number of _____one-way ☐☐☐

27. If you normally travelled by car, if you had to pay for parking, how much did you pay?

	£	pence
Expenditure on parking	☐☐	☐☐

EQ-5D-5L

☐ Baseline
☐ 12 Weeks
☐ 24 Weeks
☐ 52 Weeks
☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Instructions for person with memory problems:
Under each heading, please tick the ONE box that best describes your health TODAY.

1. Mobility

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking about
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

2. Self-Care

- ☐ I have no problems in washing or dressing myself
- ☐ I have slight problems in washing or dressing myself
- ☐ I have moderate problems in washing or dressing myself
- ☐ I have severe problems in washing or dressing myself
- ☐ I am unable to wash or dress myself

3. Usual Activities (e.g. work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

4. Pain/Discomfort

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

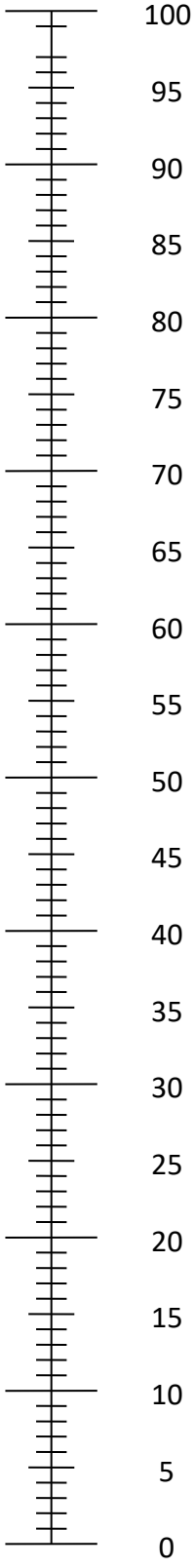
5. Anxiety/Depression

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

The best health you can imagine



The worst health you can imagine

EQ-5D-5L Proxy

☐ Baseline

☐ 12 Weeks

☐ 24 Weeks

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ATTILA Study Number

Date D D M M Y Y

Assessor Initials

Instructions for carers

By placing a tick in one box in each group below, please indicate which statement you think best describes the subject's health TODAY.

1. Mobility

- ☐ No problems in walking about
- ☐ Slight problems in walking about
- ☐ Moderate problems in walking about
- ☐ Severe problems in walking about
- ☐ Unable to walk about

2. Self-Care

- ☐ No problems in washing or dressing him/herself
- ☐ Slight problems in washing or dressing him/herself
- ☐ Moderate problems in washing or dressing him/herself
- ☐ Severe problems in washing or dressing him/herself
- ☐ Unable to wash or dress him/herself

3. Usual Activities (e.g. work, study, housework, family or leisure activities)

- ☐ No problems doing his/her usual activities
- ☐ Slight problems doing his/her usual activities
- ☐ Moderate problems doing his/her usual activities
- ☐ Severe problems doing his/her usual activities
- ☐ Unable to do his/her usual activities

4. Pain/Discomfort

- ☐ No pain or discomfort
- ☐ Slight pain or discomfort
- ☐ Moderate pain or discomfort
- ☐ Severe pain or discomfort
- ☐ Extreme pain or discomfort

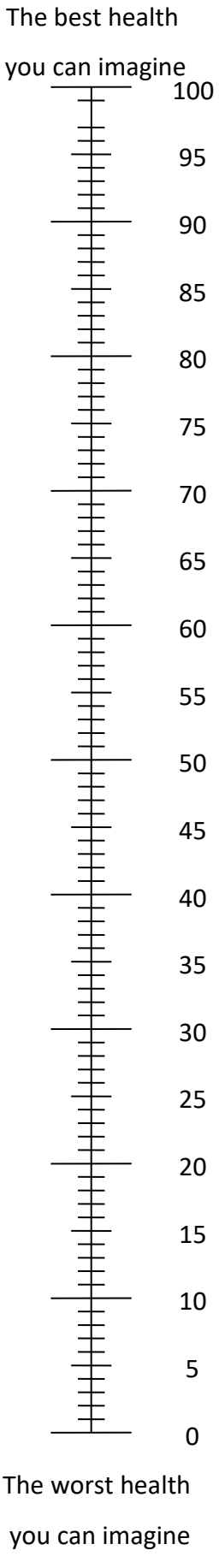
5. Anxiety/Depression

- ☐ Not anxious or depressed
- ☐ Slightly anxious or depressed
- ☐ Moderately anxious or depressed
- ☐ Severely anxious or depressed
- ☐ Extremely anxious or depressed

We would like to know how good or bad you think the subject's health is TODAY.
This scale is numbered from 0 to 100.

- 100 means the <u>best</u> health imaginable.
  0 means the <u>worst</u> health imagineable.
- Mark an X on the scale to indicate how good or bad the subject's health is TODAY.
- Now, please write the number you marked on the scale in the box below.

THE SUBJECT'S HEALTH TODAY = ☐



Zarit Burden Interview

☐ Baseline
☐ 12 Weeks
☐ 24 Weeks
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☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

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Instructions for carers:

The questions reflect how people sometimes feel when they are taking care of another person. After each statement, choose the word that best describes how often you feel that way. There are no right or wrong answers.

		(Please tick ✓one box for *each* of these question)				
	In the last month, how often…	**Never**	**Rarely**	**Some-times**	**Quite often**	**Nearly always**
1	Do you feel that the person you care for asks for more help than he/she needs?	☐	☐	☐	☐	☐
2	Do you feel that because of the time you spend with the person you care for that you don't have enough time for yourself?	☐	☐	☐	☐	☐
3	Do you feel stressed between caring for the person you care for and trying to meet other responsibilities for your family or work?	☐	☐	☐	☐	☐
4	Do you feel embarrassed over the behaviour of the person you care for?	☐	☐	☐	☐	☐
5	Do you feel angry when you are around the person you care for?	☐	☐	☐	☐	☐
6	Do you feel that the person you care for currently affects your relationships with other family members or friends in a negative way?	☐	☐	☐	☐	☐
7	Are you afraid what the future holds for the person you care for?	☐	☐	☐	☐	☐
8	Do you feel the person you care for is dependent on you?	☐	☐	☐	☐	☐
9	Do you feel strained when you are around the person you care for?	☐	☐	☐	☐	☐

10	Do you feel your health has suffered because of your involvement with the person you care for?	☐	☐	☐	☐	☐
		Never	**Rarely**	**Some-times**	**Quite Often**	**Nearly always**
11	Do you feel that you don't have as much privacy as you would like because of the person you care for?	☐	☐	☐	☐	☐
12	Do you feel your social life has suffered because you are caring for the person you care for?	☐	☐	☐	☐	☐
13	Do you feel uncomfortable about having friends over because of the person you care for?	☐	☐	☐	☐	☐
14	Do you feel that the person you care for seems to expect you to take care of him/her as if you were the only one he/she could depend on?	☐	☐	☐	☐	☐
15	Do you feel that you don't have enough money to take care of the person you care for in addition to the rest of your expenses?	☐	☐	☐	☐	☐
16	Do you feel that you will be unable to take care of the person you care for much longer?	☐	☐	☐	☐	☐
17	Do you feel you have lost control of your life since the illness/disability of the person you care for?	☐	☐	☐	☐	☐
18	Do you wish you could leave the care of the person you care for to someone else?	☐	☐	☐	☐	☐
19	Do you feel uncertain about what to do about the person you care for?	☐	☐	☐	☐	☐
20	Do you feel you should be doing more for the person you care for?	☐	☐	☐	☐	☐
21	Do you feel you could do a better job in caring for the person you care for?	☐	☐	☐	☐	☐
22	Overall, how burdened do you feel in caring for your relative?	☐	☐	☐	☐	☐

Centre for Epidemiological Studies Depression Scale (CES-D10)

☐ Baseline
☐ 12 Weeks
☐ 24 Weeks
☐ 52 Weeks
☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Instructions for carers:

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week. There are no right or wrong answers.

(Please tick ✓one box for *each* of these questions)

	During the past week…	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
1	I was bothered by things that don't usually bother me.	☐	☐	☐	☐
2	I had trouble keeping my mind on what I was doing.	☐	☐	☐	☐
3	I felt depressed.	☐	☐	☐	☐
4	I felt everything I did was an effort.	☐	☐	☐	☐
5	I felt hopeful about the future.	☐	☐	☐	☐
6	I felt tearful.	☐	☐	☐	☐
7	My sleep was restless.	☐	☐	☐	☐
8	I was happy.	☐	☐	☐	☐
9	I felt lonely.	☐	☐	☐	☐
10	I could not 'get going'.	☐	☐	☐	☐

Standard Trait Anxiety Inventory Short-form (STAI-6)

☐ Baseline
☐ 12 Weeks
☐ 24 Weeks
☐ 52 Weeks
☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Instructions for carers:

A number of statements which people have used to describe themselves are given below. Read each statement and then **tick** the appropriate box to indicate how you feel ***right now, at this moment*.** There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe your present feelings best.

		(Please tick ✓one box for *each* of these questions)			
	At the moment…	**Not at all**	**Somewhat**	**Moderately**	**Very much**
1	I feel calm.	☐	☐	☐	☐
2	I am tense.	☐	☐	☐	☐
3	I feel upset.	☐	☐	☐	☐
4	I am relaxed.	☐	☐	☐	☐
5	I feel content.	☐	☐	☐	☐
6	I am worried.	☐	☐	☐	☐

Serious Adverse Event Form

SAE Reference Number: | | | | | | (Please phone Trial Manager on 020 7848 0509 to obtain)

ATTILA Study No. | | | | | | Date | D | D | M | M | Y | Y | Assessor Initials | | | |

Definitions

In the context of the ATTILA trial:

Adverse Event (AE) = any compromise of participant safety

Serious Adverse Event (SAE) = any compromise of participant safety that:

(i) Results in death
(ii) Is life-threatening
(iii) Requires hospitalisation or prolongation of existing hospitalisation
(iv) Results in persistent or significant disability or incapacity
(v) Requires intervention of emergency services
(vi) Results in admission to permanent residential care

Procedure for reporting

Please report any **SAE**s immediately by completing all the details below and emailing or faxing this form to the ATTILA Study Office, Department of Old Age Psychiatry, Institute of Psychiatry,

1. Is this an initial or follow-up report? ☐ Initial ☐ Follow-up

2. Is this a final report? ☐ Yes ☐ No

3. Reason for reporting:

☐ Fatal event; Date of death: ____ / ____ / ____
☐ Life-threatening event
☐ Required hospitalisation; No. days: _____ or ☐ ongoing?
☐ Persistent or significant disability or incapacity
☐ Emergency services intervention
☐ Admission to permanent residential care
☐ Other reason; Please specify: _____

4. Date event started: D D M M Y Y

5. Date event ceased: D D M M Y Y or ☐ ongoing?

6. Did the SAE affect the participant's residential status?

- ☐ No, participant still resident in community
- ☐ Yes, participant now in hospital
- ☐ Yes, participant now in temporary care
- ☐ Yes, participant now in permanent care
- ☐ Participant has died

7. Details of SAE (please attach copies of relevant reports):

_____

_____

_____

_____

_____

8. Could this SAE have been prevented, or its consequences mitigated, by ATT? *(Tick most likely)*

- ☐ **Not preventable**: event/consequences would have been the same with or without ATT
- ☐ **Unlikely preventable**: event/consequences unlikely to be altered by ATT
- ☐ **Possibly preventable**: possible that event/consequences might have been prevented/mitigated by ATT
- ☐ **Likely preventable**: reasonable to believe that event/consequences might have been prevented/mitigated by ATT
- ☐ **Definitely preventable**: event/consequences would have been prevented/mitigated by ATT

9. Please state what ATT might have prevented or mitigated the consequences of this SAE and the reason this is considered to be the case:

_____

_____

_____

10. Was this risk anticipated in a professional assessment of needs?

- ☐ Yes, anticipated risk
- ☐ Possible risk
- ☐ Thought unlikely
- ☐ Unexpected risk / not identified as a risk
- ☐ Not applicable – eg SAE was due to a medical condition

11. If the risk was anticipated, was the ATT that might have prevented the SAE:

(Tick all that apply)

Recommended in a professional needs assessment?	☐ Yes	☐ No	
Installed?	☐ Yes	☐ No	☐ NA
In use?	☐ Yes	☐ No	☐ NA

Declaration

Name: _____ Position: _____

Signature: _____ Date of reporting SAE: D D M M Y Y

Email: _____ Telephone no: _____

ATTILA Follow-up Form

☐ Baseline ☐ 104 Weeks

☐ 12 Weeks ☐ Withdrawal

☐ 24 Weeks ☐ Status Check - __ __ __ weeks

☐ 52 Weeks ☐ Change of participant/carer status

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Please complete this form:

- **At each follow-up visit or status check phone call (please tick appropriate box above)**
- **When you are made aware that the participant/carer would like to discontinue follow-up visits or withdraw consent for further participation in the trial**
- **When you are made aware that the participant has been permanently admitted to care or died or that there has been any other change in status of patient or carer**

Section 1 – Participant's Current Status *(Please tick one status)*

Participant is living in the community **Yes** ☐ **No** ☐

- **Participant is in permanent** **Residential care** ☐ **Nursing care** ☐

  Date of initial admission: D D M M Y Y *(Please complete SAE form)*

  Name and address of facility: _____

  _____

- **Participant has died** ☐ **Date of death:** D D M M Y Y

  Cause of death *(Please complete SAE form)*: _____

  _____

- **Other/ unknown status** ☐ **Please specify:** _____

  _____

Section 2 – Assistive Technology

Has any ATT been installed as a consequence of the participant's allocation to the ATT arm?

Not allocated to ATT arm ☐ **No** ☐ **Yes, in use** ☐ **Yes, not in use** ☐

If Yes, please give details: _____

_____

_____

_____

_____

Have there been any deviations from the allocated intervention? **No** ☐ **Yes** ☐

If Yes, please describe: _____

_____

_____

_____

Section 3 – Participant Safety

ATTILA Adverse Event definitions

Adverse Event (AE) = any compromise of patient safety

Serious Adverse Event (SAE) = any compromise of patient safety that:

Have there been any compromises of participant safety (Adverse Events) since the last follow-up form was completed? **No** ☐ **Yes** ☐ **How many?** _____

If Yes, were any events serious? **No** ☐ **Yes** ☐ **How many?** _____
(See definition above) *(Please complete SAE form for each serious event)*

For all non-serious Adverse Events, please provide details below, using additional continuation sheets if necessary

12. Details of the AE:

13. Could this AE have been prevented, or consequences mitigated, by ATT? *(Tick most likely)*

- ☐ Not preventable: event/consequences would have been the same with or without ATT
- ☐ Unlikely preventable: event/consequences unlikely to be altered by ATT
- ☐ Possibly preventable: possible that event/consequences might have been prevented/mitigated by ATT
- ☐ Likely preventable: reasonable to believe that event/consequences might have been prevented/mitigated by ATT
- ☐ Definitely preventable: event/consequences would have been prevented/mitigated by ATT

14. Please state what ATT might have prevented or mitigated the consequences of this AE and the reason this is considered to be the case:

15. If the event might have been prevented or consequences mitigated, was the relevant ATT:
(Tick all that apply)

Recommended in a professional needs assessment?	Yes ☐	No ☐	N/A ☐
Installed?	Yes ☐	No ☐	N/A ☐
In use?	Yes ☐	No ☐	N/A ☐

Comments:

1. **Details of additional AE:**

2. **Could this AE have been prevented, or consequences mitigated, by ATT?** *(Tick most likely)*

- ☐ Not preventable: event/consequences would have been the same with or without ATT
- ☐ Unlikely preventable: event/consequences unlikely to be altered by ATT
- ☐ Possibly preventable: possible that event/consequences might have been prevented/mitigated by ATT
- ☐ Likely preventable: reasonable to believe that event/consequences might have been prevented/mitigated by ATT
- ☐ Definitely preventable: event/consequences would have been prevented/mitigated by ATT

3. **Please state what ATT might have prevented or mitigated the consequences of this AE and the reason this is considered to be the case:**

4. **If the event might have been prevented or consequences mitigated, was the relevant ATT:**
(Tick all that apply)

Recommended in a professional needs assessment?	Yes ☐	No ☐	N/A ☐
Installed?	Yes ☐	No ☐	N/A ☐
In use?	Yes ☐	No ☐	N/A ☐

Comments:

---

1. **Details of additional AE:**

2. **Could this AE have been prevented, or consequences mitigated, by ATT?** *(Tick most likely)*

- ☐ Not preventable: event/consequences would have been the same with or without ATT
- ☐ Unlikely preventable: event/consequences unlikely to be altered by ATT
- ☐ Possibly preventable: possible that event/consequences might have been prevented/mitigated by ATT
- ☐ Likely preventable: reasonable to believe that event/consequences might have been prevented/mitigated by ATT
- ☐ Definitely preventable: event/consequences would have been prevented/mitigated by ATT

3. **Please state what ATT might have prevented or mitigated the consequences of this AE and the reason this is considered to be the case:**

4. **If the event might have been prevented or consequences mitigated, was the relevant ATT:**
(Tick all that apply)

Recommended in a professional needs assessment?	Yes ☐	No ☐	N/A ☐
Installed?	Yes ☐	No ☐	N/A ☐
In use?	Yes ☐	No ☐	N/A ☐

Comments:

Section 4 – Further follow-up

Has there been any change of carer status? No ☐ Yes ☐

If yes, date of change: D D M M Y Y

Cause of change: _____

Will this result in a change to the carer who would complete questionnaires?

No ☐ Yes ☐ Name of new carer: _____

Please ensure that a new Carer Consent form is completed and the Demographic Questionnaire is repeated with the new carer

Are the participant and carer willing to continue follow-up visits? ☐ Yes ☐ No

If no, please explain why they wish to cease visits:

_____

_____

_____

_____

Are the participant and carer willing to receive a residential status check phone call in place of visits?

No ☐ Yes ☐ Telephone Number: .....

If no, are the patient and carer willing to be contacted by the study team by telephone at end of the study period to ascertain residential status?

No ☐ Yes ☐ Telephone Number: .....

Have all the required questionnaires been completed?

- ☐ Demographic Questionnaire (Baseline only)
- ☐ sMMSE (Baseline only)
- ☐ BADLS (Baseline & Week 104)
- ☐ EQ-5D-5L
- ☐ EQ-5D-5L Proxy
- ☐ SF-12
- ☐ STAI-6
- ☐ CES-D10
- ☐ Zarit Burden Interview
- ☐ SUTAQ
- ☐ CSRI
- ☐ Technology Checklist

If any questionnaires have not been completed, why not?

_____

_____

_____

_____

_____

If this is your last visit, would you like to receive the trial results when they are published?

No ☐ Yes ☐ Address: .....

.....

.....

Service User Technology Acceptance Questionnaire (SUTAQ)

☐ 12 Weeks
☐ 24 Weeks
☐ 52 Weeks
☐ 104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Instructions for carer:

Below is a list of statements referring to the kit (Assistive Technology) that the person you care for has received to support their care. Please indicate the degree to which you agree with each statement. There are no right or wrong answers.

Is any of the kit monitored? ☐ Yes (Please answer all questions) ☐ No (Please only answer questions on page 2)

If any is monitored, is this by: ☐ Unpaid carer ☐ Professional Service ☐ Both

Please complete for monitored Assistive Technology only

(Please tick ✓one box for *each* of these questions)

		Strongly agree	Moderately agree	Mildly agree	Mildly disagree	Moderately disagree	Strongly disagree
1	I am concerned that the person who monitors the information from the kit does not know the social/health care history of the person I care for	☐	☐	☐	☐	☐	☐
2	The kit received by the person I care for has invaded my privacy	☐	☐	☐	☐	☐	☐
3	I am concerned about the level of expertise of the people who monitor the kit	☐	☐	☐	☐	☐	☐
4	The kit makes me worried about the confidentiality of the private information being exchanged through it	☐	☐	☐	☐	☐	☐
5	The social and health care professionals are better able to monitor the condition of the person I care for using the kit	☐	☐	☐	☐	☐	☐
6	The kit has made it easier to get in touch with social and/or health care professionals	☐	☐	☐	☐	☐	☐
7	The kit interferes with the continuity of the care received by the person I care for (i.e. they do not have contact with same care professional each time)	☐	☐	☐	☐	☐	☐

Please complete for all Assistive Technology

(Please tick ✓one box for *each* of these questions)

		Strongly agree	Moderately agree	Mildly agree	Mildly disagree	Moderately disagree	Strongly disagree
8	The kit has saved me time as there is a reduced need to interact with social care and health care professionals	☐	☐	☐	☐	☐	☐
9	The kit has interfered with my everyday routine	☐	☐	☐	☐	☐	☐
10	The kit has made it easier for me to access care (i.e. social/health care professionals) on behalf of the person I care for	☐	☐	☐	☐	☐	☐
11	The kit has been explained to me sufficiently	☐	☐	☐	☐	☐	☐
12	The kit can be trusted to work appropriately	☐	☐	☐	☐	☐	☐
13	The kit has made me feel uncomfortable, e.g. emotionally or physically	☐	☐	☐	☐	☐	☐
14	Since the kit was installed, I am less worried about the social care, safety, or health care of the person I care for	☐	☐	☐	☐	☐	☐
15	The kit has made me more actively involved in the social and/or health care of the person I care for	☐	☐	☐	☐	☐	☐
16	I am satisfied with the kit received by the person I care for	☐	☐	☐	☐	☐	☐
17	I would recommend the kit to people with a similar condition or social care needs to the person I care for	☐	☐	☐	☐	☐	☐
18	The kit can be a replacement for the regular social or health care of the person I care for	☐	☐	☐	☐	☐	☐
19	The kit can be a good addition to the regular social or health care of the person I care for	☐	☐	☐	☐	☐	☐
20	The kit is not as suitable for me as regular face-to-face social or health care	☐	☐	☐	☐	☐	☐
21	Since the kit has been installed, I am less worried about the safety or health status of the person I care for	☐	☐	☐	☐	☐	☐
22	The kit has helped to improve the safety and/or health of the person I care for	☐	☐	☐	☐	☐	☐

Bristol Activities of Daily Living Scale (BADLS)

☐ Baseline

☐104 Weeks or Withdrawal

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | | |

Instructions for carers:

This questionnaire is designed to reveal the everyday ability of people who have memory difficulties of one form or another.

For each activity, statements a-e refers to a different level of ability. Thinking of the last 2 weeks, tick the letter that represents your relative's/friend's ability.

Only 1 letter should be ticked for each activity.

If in doubt about which to tick, choose the level of ability which represents their average performance over the last 2 weeks.

1. Food

☐ a. Selects and prepares food as required
☐ b. Able to prepare food if ingredients are set out
☐ c. Can prepare food if prompted step by step
☐ d. Unable to prepare food even with prompting and supervision
☐ e. Not applicable

2. Eating

☐ a. Eats appropriately using correct cutlery
☐ b. Eats appropriately if food made manageable and/or uses spoon
☐ c. Uses fingers to eat food
☐d. Needs to be fed
☐ e. Not applicable

3. Drink

☐ a. Selects and prepares drinks as required
☐ b. Can prepare drinks if ingredients left available
☐ c. Can prepare drinks if prompted step by step
☐ d. Unable to make a drink even with prompting and supervision
☐ e. Not applicable

4. Drinking

☐ a. Drinks appropriately
☐ b. Drinks appropriately with aids (beaker/straw etc.)
☐ c. Does not drink appropriately even with aids, but attempts to
☐ d. Has to have drink administered (fed)
☐ e. Not applicable

5. Dressing

☐ a. Selects appropriate clothing and dresses self
☐ b. Puts clothes on in wrong order or back to front or dirty clothing
☐ c. Unable to dress self but moves limbs to assist
☐ d. Unable to assist and requires total dressing
☐ e. Not applicable

6. Hygiene

☐ a. Washes regularly and independently
☐ b. Can wash self if given soap, flannel, towel, etc.
☐ c. Can wash self if prompted and supervised
☐ d. Unable to wash self and needs full assistance
☐ e. Not applicable

7. Teeth

☐ a. Cleans own teeth/dentures regularly and independently
☐ b. Cleans teeth/dentures if given appropriate items
☐ c. Requires some assistance, toothpaste on brush, brush to mouth, etc.
☐ d. Full assistance given
☐ e. Not applicable

8. Bath/Shower

☐ a. Bathes regularly and independently
☐ b. Needs bath to be run/shower turned on, but washes independently
☐ c. Needs supervision and prompting to wash
☐ d. Totally dependent, needs full assistance
☐ e. Not applicable

9. Toilet/Commode

☐ a. Uses toilet appropriately when required
☐ b. Needs to be taken to the toilet and given assistance
☐ c. Incontinent of urine or faeces
☐ d. Incontinent of urine and faeces
☐ e. Not applicable

10. Transfers

☐ a. Can get in/out of chair unaided
☐ b. Can get into a chair but needs help to get out
☐ c. Needs help getting in and out of a chair
☐ d. Totally dependent on being put into and lifted from chair
☐ e. Not applicable

11. Mobility

☐ a. Walks independently
☐ b. Walks with assistance, i.e. furniture, arm for support
☐ c. Uses aids to mobilize, i.e. frame, sticks etc.
☐ d. Unable to walk
☐ e. Not applicable

12. Orientation - time

☐ a. Fully orientated to time/day/date etc.
☐ b. Unaware of time/day etc. but seems unconcerned
☐ c. Repeatedly asks the time/day/date
☐ d. Mixes up night and day
☐ e. Not applicable

13. Orientation - Space

☐ a. Fully orientated to surroundings
☐ b. Orientated to familiar surroundings only
☐ c. Gets lost in home, needs reminding where bathroom is, etc.
☐ d. Does not recognise home as own and attempts to leave
☐ e. Not applicable

14. Communications

☐ a. Able to hold appropriate conversation
☐ b. Shows understanding and attempts to respond verbally or with gestures
☐ c. Can make self understood but difficulty understanding others
☐ d. Does not respond to or communicate with others
☐ e. Not applicable

15. Telephone

☐ a. Uses telephone appropriately, including obtaining correct number
☐ b. Uses telephone if number given verbally/visually or predialled
☐ c. Answers telephone but does not make calls
☐ d. Unable/unwilling to use telephone at all
☐ e. Not applicable

16. Gardening/Housework

☐ a. Able to do housework/gardening to previous standard
☐ b. Able to do housework/gardening but not to previous standard
☐ c. Limited participation even with a lot of supervision
☐ d. Unwilling/unable to participate in previous activities
☐ e. Not applicable

17. Shopping

☐ a. Shops to previous standard
☐ b. Only able to shop for 1 or 2 items with or without a list
☐ c. Unable to shop alone, but participates when accompanied
☐ d. Unable to participate in shopping even when accompanied
☐ e. Not applicable

18. Finances

☐ a. Responsible for own finances at previous level
☐ b. Unable to write cheques but can sign name and recognises money values
☐ c. Can sign name but unable to recognise money values
☐ d. Unable to sign name or recognise money values
☐ e. Not applicable

19. Games/Hobbies

☐ a. Participates in pastimes/activities to previous standard
☐ b. Participates but needs instruction/supervision
☐ c. Reluctant to join in, very slow, needs coaxing
☐ d. No longer able to willing to join in
☐ e. Not applicable

20. Transport

☐ a. Able to drive, cycle or use public transport independently
☐ b. Unable to drive but uses public transport or bike etc.
☐ c. Unable to use public transport alone
☐ d. Unable/unwilling to use transport even when accompanied
☐ e. Not applicable

Standardised Mini-Mental State Examination (sMMSE)

☐ Baseline

ATTILA Study Number | | | | | |

Date D D M M Y Y

Assessor Initials | | |

Instructions for person with memory problems:

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

ITEM		SCORE
1 Time Orientation		
Ask:		
• What is the year?	_____	**/1**
• Which season is this?	_____	**/1**
• What month is this?	_____	**/1**
• What is today's date?	_____	**/1**
• What day of the week is this?	_____	**/1**
2 Place Orientation		
Ask:		
• What country are we in?	_____	**/1**
• What county?	_____	**/1**
• What city/town are we in?	_____	**/1**
• What is the street address of this house?	_____	**/1**
• What room are we in?	_____	**/1**

3 Registration of Three Words

Say:

I am going to name three objects. When I am finished, I want you to repeat them.

Remember what they are because I am going to ask you to name them again in a few minutes.

Say the following words slowly at 1-second intervals.

Ball Car Man **/3**

4 Spell the word WORLD. Now spell it backwards. **/5**

5 Recall of Three Words

What were those three objects I asked you to remember?

- _____ **/1**
- _____ **/1**
- _____ **/1**

Naming

Ask:

6 What is this called? (Show watch) _____ **/1**

7 What is this called? (Show pencil) _____ **/1**

8 Repetition

Say:

I would like you to repeat what I say. ***NO IFS, ANDS OR BUTS***

_____ **/1**

9 Reading

Say:

Read the words on the page and then do what it says.

Hand the person the sheet with 'CLOSE YOUR EYES' on it. **/1**

10 Writing

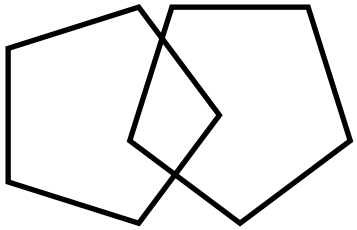
Say:

Write any complete sentence on that piece of paper. (Note: The sentence must make sense. Ignore spelling errors.). **/1**

11 Drawing

Place design, eraser and pencil in front of person.

Say: Copy this design please.



Allow multiple tries. Wait until the person is finished and hands it back. Score only for correctly copied diagram with a 4-sided figure between two 5-sided figures. **/1**

12 Comprehension

Ask if the person if they are right or left handed. Take a piece of paper and hold it up in front of the person.

Say: Take this paper in your right/left hand (non-dominant hand)**,** fold the paper in half once with both hands**,** and put the paper down on the floor**.** **/3**

Total:

10 Writing

11 Drawing