



Sugar or Salt trial:
Hyperosmolar therapy in
traumatic brain injury

TNO:

--	--	--	--

6 Month Follow-up Questionnaire

**For assistance with completing this booklet please
contact the SOS trial team on 02476 151 738**

Please read the instructions in this booklet carefully



University Hospitals Birmingham
NHS Foundation Trust



FUNDED BY

NIHR | National Institute
for Health Research

The SOS trial is funded by the National Institute for Health Research Health Technology Assessment programme (17/120/01).

TNO:

--	--	--	--

- Please read these instructions before completing the questionnaires.
- Please follow the instructions for each section carefully.
- Please answer **ALL** the questions. Although it may seem that the questions are asked more than once, it is still important that you answer every one.
- Please only enter **one** response for each item (unless otherwise specified).
- Please use a **BLACK** pen. Please do not use a pencil.
- Please check that you have completed all sections.
- If you make a mistake draw a single line through the incorrect entry, initial and date and add correct answer next to the incorrect entry.
- Please **DO NOT** use correction fluid

TNO:

--	--	--	--

Please let us know the date you are completing this questionnaire:

Date of completion: _____ / _____ / _____
dd mmm yyyy

Please let us know who will complete this questionnaire:

- ☐ The patient alone
- ☐ The patient with help from relative/ friend/ carer
- ☐ Relative/friend/carers on behalf of the patient

In this questionnaire, we use the words “you” and “your” referring to **the person who sustained the brain injury**. Some people in this study may have a medical condition or disability that would prevent them to fill in these questionnaires themselves. In that case, a relative/friend/ carer can fill out the questionnaires, however the words “you” and “your” still refer to **the person who sustained the brain injury** and not to the person helping/assisting in filling out the questionnaires.

TNO:

--	--	--	--

For each question please select the response that best describes your answer by marking (✓) the appropriate box.

Part 1. Consciousness

A. Are you able to obey simple commands or say any words?

Note: obeying commands is considered anyone who shows the ability to obey even simple commands or utter any word or communicate specifically in any other way. Eye movements alone are not reliable evidence of meaningful responsiveness.

☐ NO

☐ YES

Part 2. Independence at home

A. Is the assistance of another person at home essential every day for some activities of daily living?

Note: for a NO answer you should be able to look after yourself at home for 24 hours if necessary. Not requiring assistance means that you have the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers and handling minor domestic crises. You should be able to carry out activities without needing prompting or reminding and should be capable of being left alone overnight.

☐ NO – GO TO PART 3

☐ YES – Please give details about the number of visit(s) below

B. Do you need frequent help or someone to be around at home most of the time?

Note: for a NO answer you should be able to look after yourself at home up to 8 hours during the day if necessary.

☐ NO

☐ YES

C. Was assistance at home essential before the injury?

☐ NO

☐ YES

TNO:

--	--	--	--

Part 3. Independence outside home

A. Are you able to shop without assistance?

Note: this includes being able to plan what to buy, take care of money yourself and behave appropriately in public.

☐ NO

☐ YES

B. Were you able to shop without assistance before?

☐ NO

☐ YES

Part 4. Independence outside home - 2

A. Are you able to travel locally without assistance?

Note: you may drive or use public transport to get around. Ability to use a taxi is sufficient, provided that you person can phone for it yourself and instruct the driver.

☐ NO

☐ YES

B. Were you able to travel locally without assistance before the injury?

☐ NO

☐ YES

Part 5. Work

A. Are you currently able to work (or look after others at home) to your previous capacity?

☐ NO

☐ YES – GO TO PART 6

TNO:

--	--	--	--

B. How restricted are you?

- ☐ a. Reduced work capacity
- ☐ b. Able to work only in a sheltered workshop **or** non-competitive job **or** currently unable to work

C. Were you either working or seeking employment before the injury (answer is 'Yes') or were you doing neither (answer is 'No')?

- ☐ NO
- ☐ YES

Part 6. Social and Leisure activities

A. Are you able to resume regular social and leisure activities outside home?

Note: you need not have resumed all your previous leisure activities, but should not be prevented by physical or mental impairment. If you have stopped the majority of activities because of loss of interest or motivation, then this is also considered a 'No' answer.

- ☐ NO
- ☐ YES – GO TO PART 7

B. What is the extent of restriction on your social and leisure activities?

- ☐ a. Participate a bit less: at least half as often as before injury
- ☐ b. Participate much less: less than half as often
- ☐ c. Unable to participate: rarely, if ever, take part

C. Did you engage in regular social and leisure activities outside home before injury?

- ☐ NO
- ☐ YES

TNO:

--	--	--	--

Part 7. Family and friendships

A. Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?

Note: typical post-traumatic personality changes are: quick temper, irritability, anxiety, insensitivity to others, mood swings, depression and unreasonable or childish behaviour.

☐ NO – GO TO PART 8

☐ YES

B. What has been the extent of disruption or strain?

☐ a. Occasional - less than weekly

☐ b. Frequent - once a week or more, but not tolerable

☐ c. Constant - daily and intolerable

C. Were there problems with family or friends before injury?

Note: if there were some problems before injury, but these have become markedly worse since the injury then answer 'No' to question

☐ NO

☐ YES

EPILEPSY

D. Since the injury have you had any epileptic fits?

☐ NO

☐ YES

E. Have you been told that you are currently at risk of developing epilepsy?

☐ NO

☐ YES

TNO:

--	--	--	--

Part 8. Return to normal life

A. Are there any other current problems relating to the injury which affect daily life?

Note: other typical problems reported after head injury: headaches, dizziness, sensitivity to noise or light, slowness, memory failures and concentration problems.

☐ NO

☐ YES

B. Were similar problems present before your injury?

Note: if there were some problems before injury, but these have become markedly worse since injury then please answer 'No'

☐ NO

☐ YES

Part 9. Return to normal life - 2

A. What is the most important factor affecting your outcome?

☐ The effects of head injury?

☐ Effects of illness or injury to another part of the body?

☐ A mixture of these?

TNO:

--	--	--	--

Under each heading, please tick the ONE box that best describes your health **TODAY**

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 ☐

SELF-CARE

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

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 ☐

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 ☐

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**.

The scale is numbered from 0 to 100.

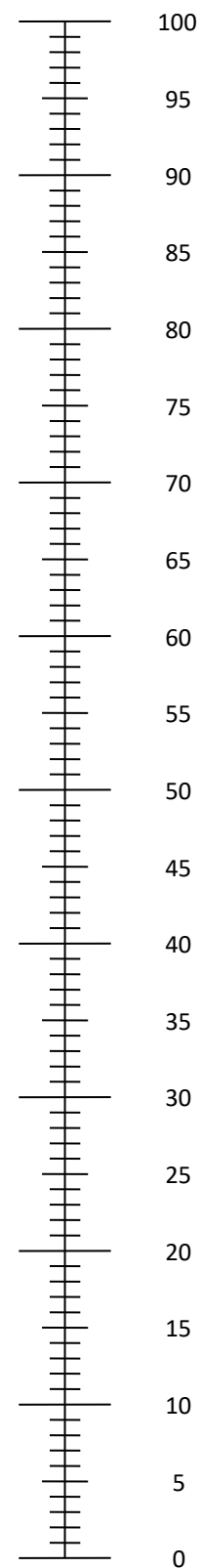
100 means the best health you can imagine.

0 means the worst 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
Page **10** of **15**

--	--	--	--

Resource use questions

1. In the last three months, have you used any of the following hospital based care services related to your brain injury (for example, have you been admitted to hospital again or had an outpatient clinic appointment)?

☐

If you have not yet been discharged from hospital since your brain injury, please tick this box and proceed to Q2.

Type of service	Have you used this service since your brain injury? Please tick (✓) yes or no	If yes, please write the total number of visits/days spent in this column
Hospital inpatient stay	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ days
Hospital outpatient clinic	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ visits
Hospital accident and emergency department	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ visits
Other (please specify)	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ visits/days (please delete as appropriate)

--	--	--	--

2. **In the last three months**, have you needed residential nursing care (e.g. step-down facilities, community ward, nursing home)?

Type of service	Have you needed this type of care since your brain injury? Please tick (✓) yes or no	If yes, how many days did you spend receiving such care?	Was this NHS funded or privately funded (either out-of-pocket or through private insurance)?
a. Community ward	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ days	NHS <input type="checkbox"/> Private <input type="checkbox"/>
b. Rehabilitation unit	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ days	NHS <input type="checkbox"/> Private <input type="checkbox"/>
c. Nursing home/care home	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ days	NHS <input type="checkbox"/> Private <input type="checkbox"/>
d. Other (please specify)	No <input type="checkbox"/> Yes <input type="checkbox"/>	_____ days	NHS <input type="checkbox"/> Private <input type="checkbox"/>

3. **In the last three months**, have you used any of the following *community* based health and social services (this includes any services that are not within the hospital for example, visits to the GP)?

☐ **If you have not yet been discharged from hospital since your brain injury, please tick this box and proceed to Q5.**

Type of service	Have you used the service since your brain injury? Please tick (✓) yes or no	If yes, please write the total number of visits/contacts in this column
a. GP, surgery visit	No <input type="checkbox"/> Yes <input type="checkbox"/>	
b. GP, home visit	No <input type="checkbox"/> Yes <input type="checkbox"/>	
c. GP, telephone contact	No <input type="checkbox"/> Yes <input type="checkbox"/>	

d. GP practice nurse	No <input type="checkbox"/> Yes <input type="checkbox"/>	
e. District nurse, health visitor or member of community health team	No <input type="checkbox"/> Yes <input type="checkbox"/>	
f. Community physiotherapist	No <input type="checkbox"/> Yes <input type="checkbox"/>	
g. Call to NHS Direct	No <input type="checkbox"/> Yes <input type="checkbox"/>	
h. Call for ambulance or paramedic	No <input type="checkbox"/> Yes <input type="checkbox"/>	
i. Occupational therapist	No <input type="checkbox"/> Yes <input type="checkbox"/>	
j. Social worker	No <input type="checkbox"/> Yes <input type="checkbox"/>	
k. Counsellor	No <input type="checkbox"/> Yes <input type="checkbox"/>	
l. Home help or care worker	No <input type="checkbox"/> Yes <input type="checkbox"/>	
m. Day centre	No <input type="checkbox"/> Yes <input type="checkbox"/>	
n. Lunch or social club (organised by health or social care providers)	No <input type="checkbox"/> Yes <input type="checkbox"/>	
o. Food, medicine or laundry delivery service (organised by health or social care providers)	No <input type="checkbox"/> Yes <input type="checkbox"/>	
p. Family or patient support or self help groups	No <input type="checkbox"/> Yes <input type="checkbox"/>	
q. Other (please specify, for example have you had any telephone consultations with your GP): 	No <input type="checkbox"/> Yes <input type="checkbox"/>	

Special Equipment or aids

4. Have you used any special equipment or aids provided by health or social services or other providers to help you in the last three months (e.g. wheelchair, stair handrails)?

No ☐ Yes ☐

- 4.1 If **yes**, please describe below the equipment or aids provided to you, and any costs incurred for their use.

Description of equipment or aid used	Who provided it? (e.g. health services, social services, self)	Cost to you (if none, please write '0')
		£
		£
		£
		£

Additional Information

5. Are you in regular work (this includes full or part-time, paid or unpaid e.g. as an unpaid carer)?

No ☐ Yes ☐

- 5.1 If yes, how many days were you unable to work because of health problems in the last three months?

days

TNO:

--	--	--	--

V2.0 26th Oct 2021

THANK YOU FOR FILLING IN THE QUESTIONNAIRE

Please return to the study team using the pre paid envelope provided (no postage stamp required)

SOS TRIAL

Warwick Clinical Trials Unit
Warwick Medical School, The University of Warwick
Coventry, CV4 7AL.