Oral healthcare for people with acute dysphagic stroke: results from the CHOSEN feasibility study

Craig J Smith[1,2,3] on behalf of the CHOSEN Investigators

[1]University of Manchester Division of Cardiovascular Sciences

[2]Geoffrey Jefferson Brain Research Centre

[3]Manchester Centre for Clinical Neurosciences, Salford Royal Hospital, MAHSC, Northern Care Alliance

craig.smith-2@manchester.ac.uk @cjsmithdr

MANCHESTER 1824 The University of Manchester

Manchester Centre for Clinical Neurosciences

NHS Northern Care Alliance NHS Group

Manchester Academic Health Science Centre

Brain Inflammation Group

Geoffrey Jefferson Brain Research Centre

Disclosures

I have received research funding from:

NIHR | National Institute for Health Research

Stroke association

MRC Medical Research Council

Fondation Leducq

THE JON MOULTON CHARITY TRUST

NIH National Institutes of Health

Fred and Maureen Done Charitable Trust

Oral-B®

Kindly provided powered brushes but had no other role in the CHOSEN trial

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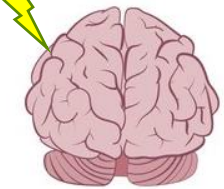
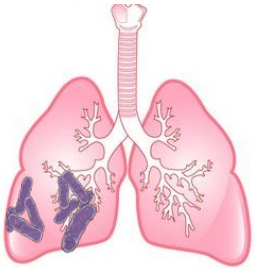
Pneumonia complicating stroke

ACUTE STROKE



Non-modifiable risk factors
- Age
- Stroke location
- Pre-stroke disability

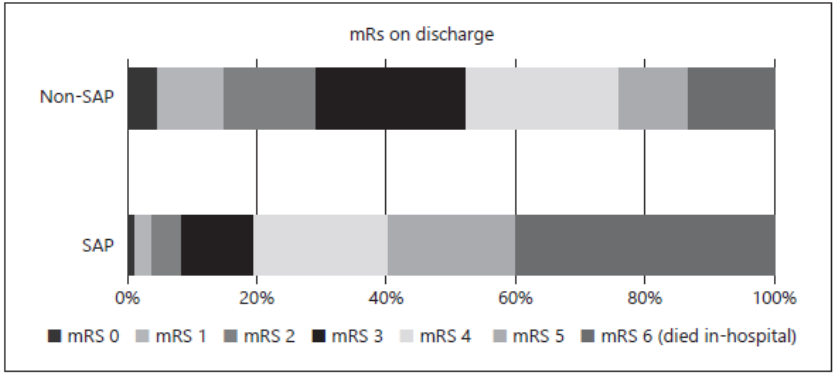
≤7 days

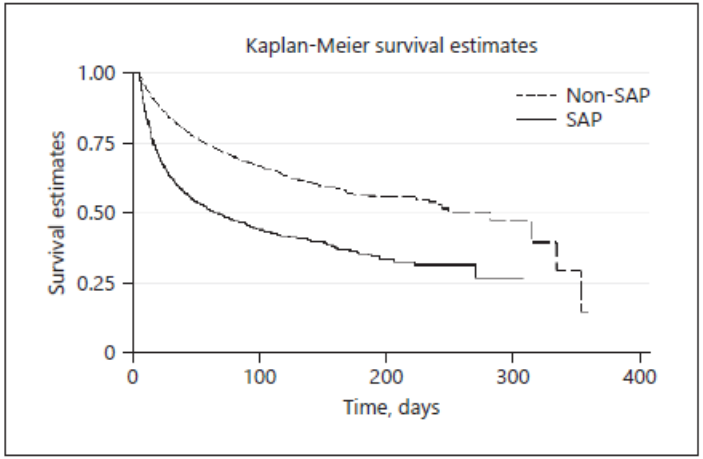


9-14%

Modifiable risk factors
- Stroke severity
- Dysphagia
- Immunity
- Oral bioburden

Worse clinical outcomes





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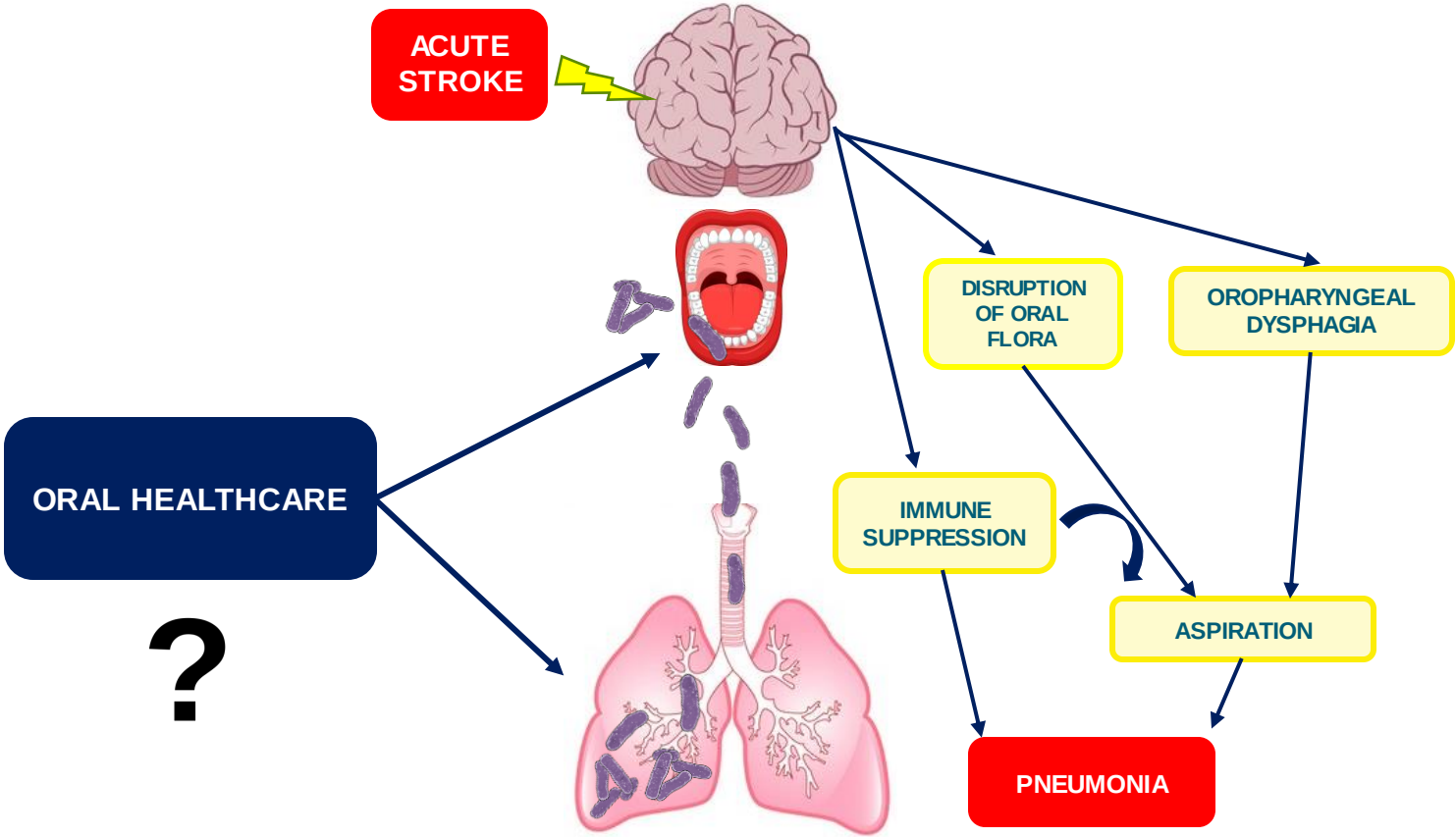
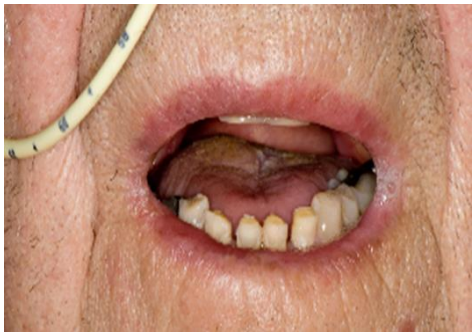
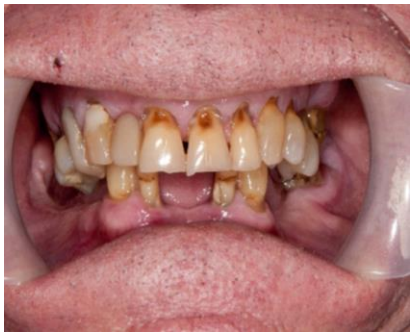
Kishore A et al, 2015; Gittins M et al, 2023; Lobo Chaves MA et al, 2023

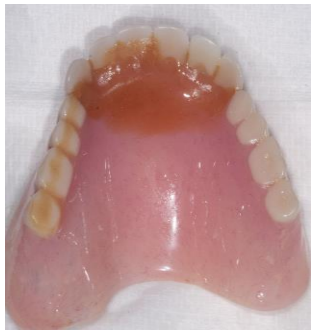

ACUTE STROKE
DISRUPTION OF ORAL FLORA
OROPHARYNGEAL DYSPHAGIA
ORAL HEALTHCARE
?
IMMUNE SUPPRESSION
ASPIRATION
PNEUMONIA

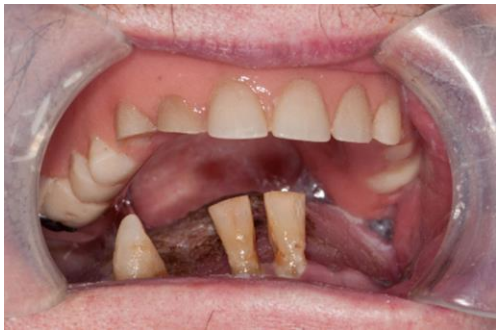
Which interventions, when and how (and how long)?

ACUTE → REHABILITATION → COMMUNITY





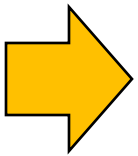




?

What is CHOSEN?

CHlorhexidine **O**r toothpa**S**te, manual or powered brushing to pr**E**vent p**N**eumonia complicating stroke (**CHOSEN**): a 2x2 factorial randomised controlled feasibility trial

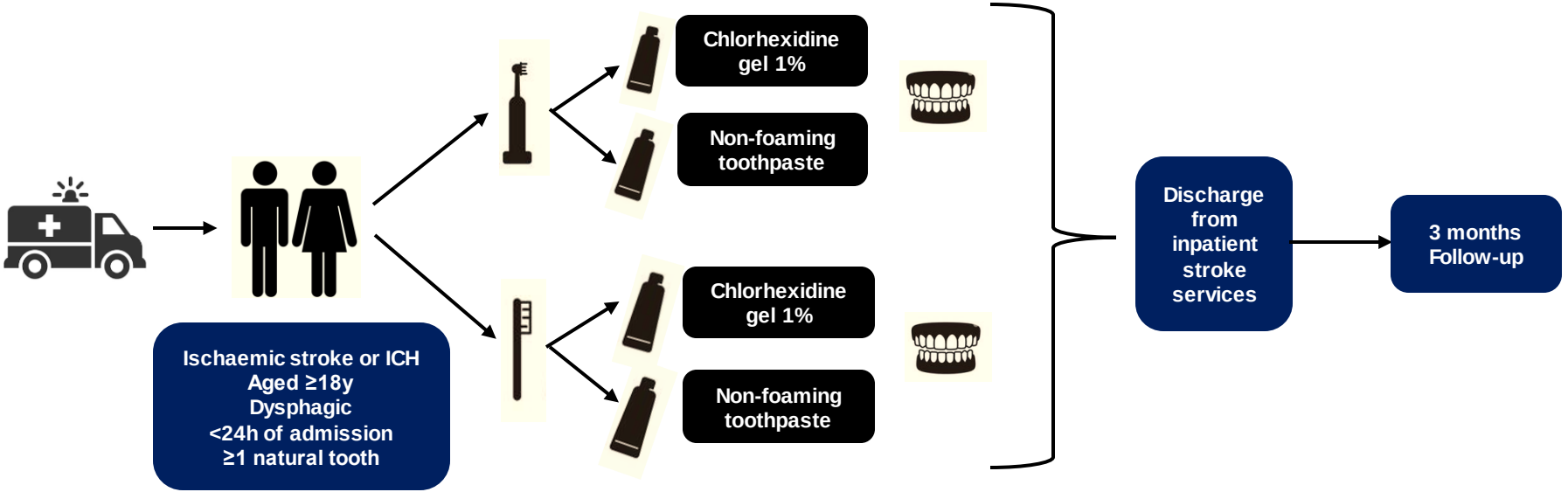


Patient and public involvement
Feasibility trial
Process evaluation

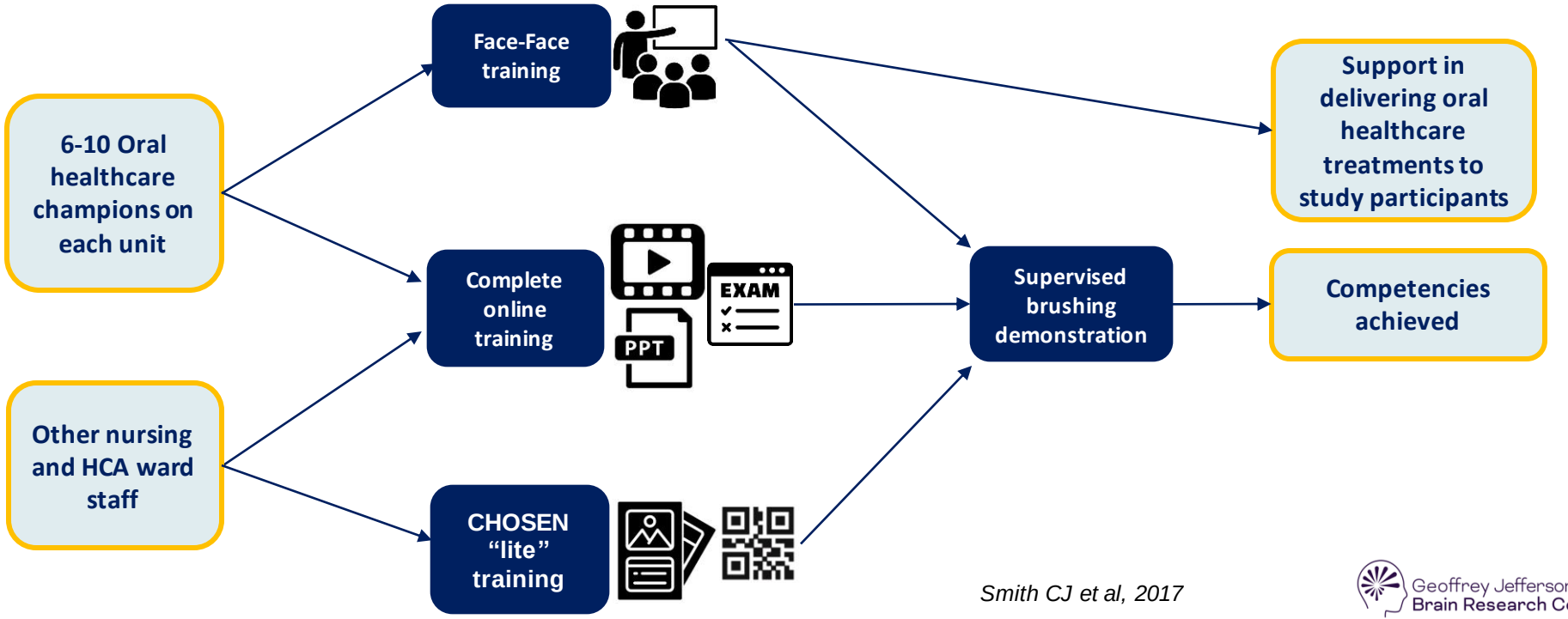
Objectives

1. Can planned recruitment of study sites and patients be achieved within the required timescale?
2. What proportion of eligible patients will participate and complete the study?
3. Will participants adhere to the allocated OHC treatments?
4. Are the OHC treatments acceptable to patients, their carers and staff?
5. Are the OHC treatments well-tolerated by patients?
6. What are the facilitators and barriers to delivery of the OHC treatments and the education/training?
7. How appropriate are the outcome measures and can they be collected?

CHOSEN trial design



CHOSEN stroke unit staff education and training



Smith CJ et al, 2017

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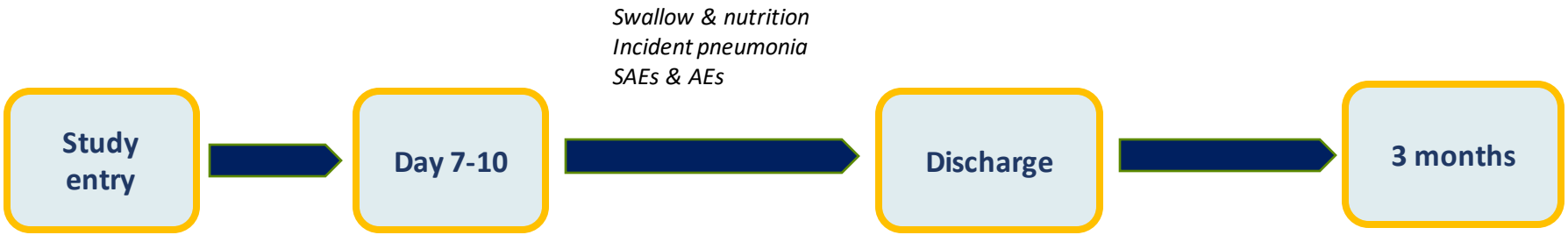
Data collection and outcome measures



Age, Sex Stroke subtype
NIHSS score
Vascular risk factors
Medications
Pre-stroke mRS
THROAT
Number of natural teeth
denture status
GOHAI
Nutrition status

THROAT
GOHAI
Swallow & nutrition
Incident pneumonia
Antibiotic doses
SAEs & AEs

WEEKLY

Fidelity/adherence
Tolerability
GOHAI
EuroQoL-5D-5L
mRS
Length of stay
Discharge destination
Incident pneumonia
Antibiotic doses

Survival
mRS
Mouth care

NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin Scale; GOHAI: General Oral Health Assessment Index; SAE: Serious Adverse Event; AE: Adverse Event

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Recruitment and set-up of participating sites

	Date training started	Green light
Salford	07/10/2021	05/01/22
Fairfield	21/09/2021	12/01/22
Preston	02/09/2021	13/01/22
Whiston	29/10/2021	19/01/22

All 4 sites were set-up with training completed over a 3-4 months period

GO	**≥3 sites**
REVIEW	**2 sites**
STOP	**1 site**

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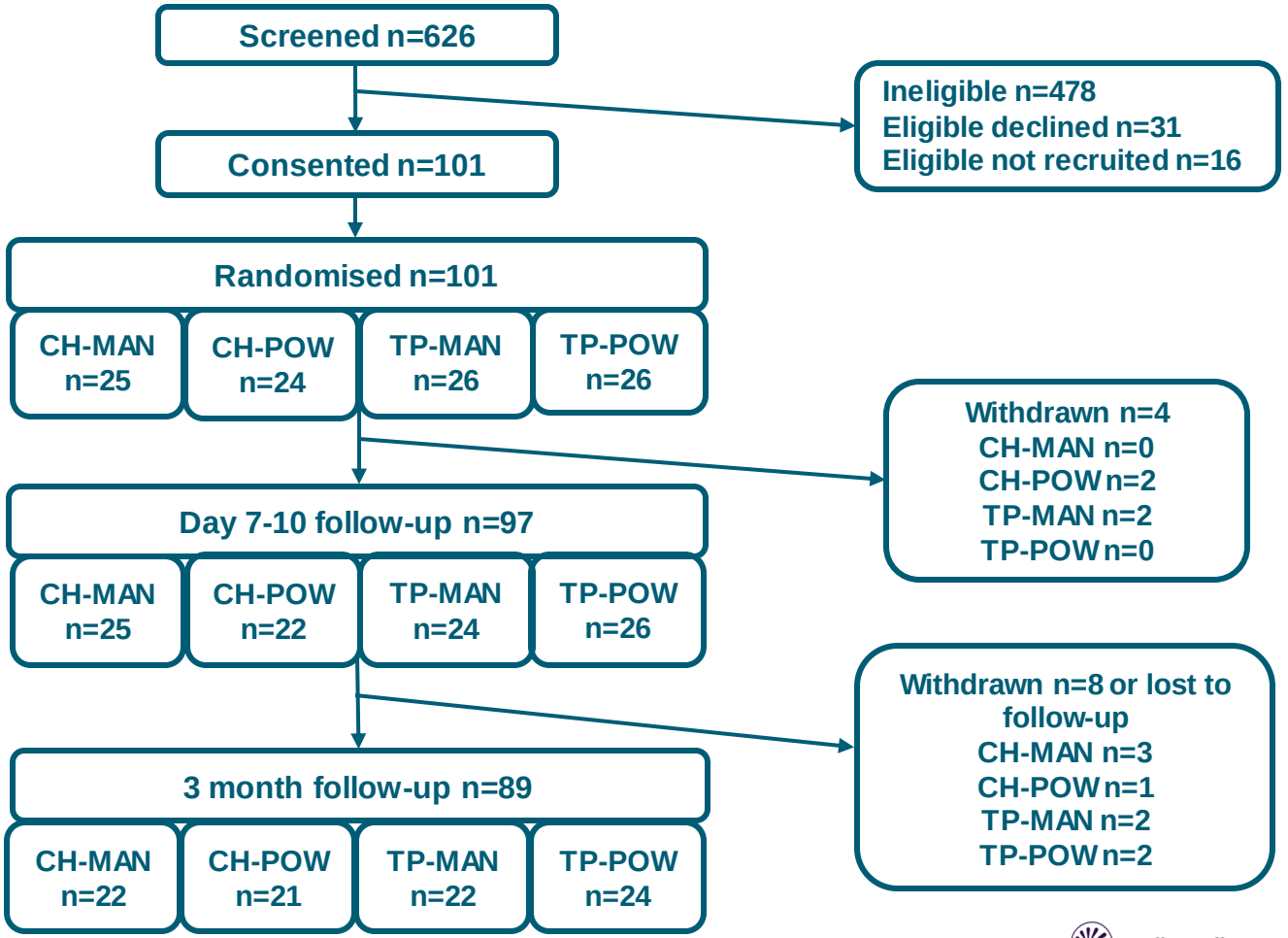
Study flow chart

n=148 eligible
n=132 eligible approached
n=101 (77%) recruited

n=89 (88%) completed follow-up
No differences in withdrawals between allocated groups



Criteria (%)	
GO	≥60
REVIEW	40-59
STOP	<40

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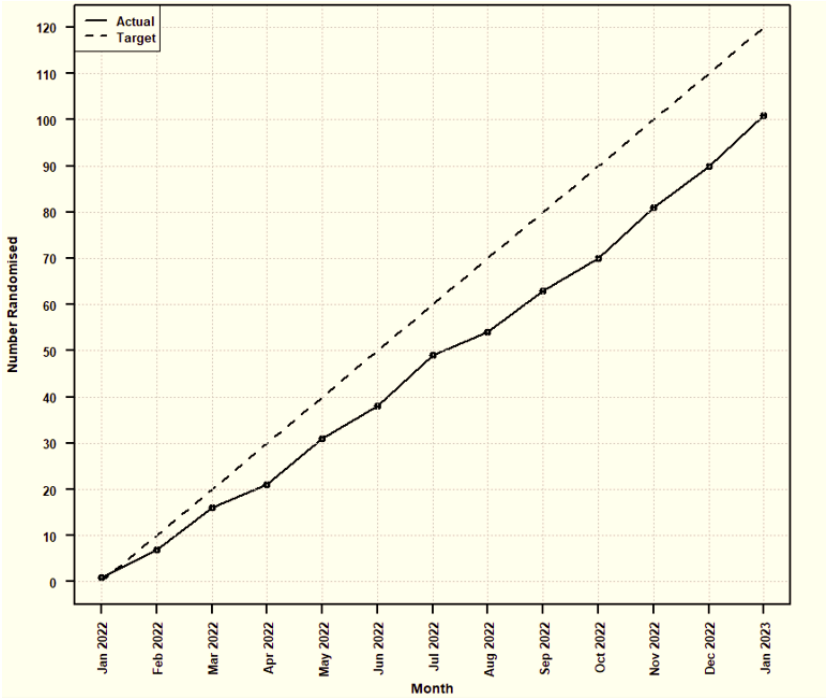
Patient recruitment



Target = 120
Actual = 101
Around 8 participants/month

	Green light	First patient recruited	Total number recruited
Salford	05/01/22	21/01/22	37
Fairfield	12/01/22	07/02/2022	26
Preston	13/01/22	10/03/22	20
Whiston	19/01/22	07/02/22	18

	Criteria (%)	Actual number
GO	**≥85**	**≥102**
REVIEW	**42-84**	**51-101**
STOP	**<42**	**<50**

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Characteristics of participating patients

No differences between participating sites or between allocated treatment groups

Characteristic	
Age (y)*	76 (65, 84)
Female	44 (44)
Ischaemic stroke	80 (79)
NIHSS*	10 (5 ,18)
Number of teeth*	18 (11.5, 20)
Dentures	28 (28)
THROAT score*	3 (2, 5.25)
GOHAI*	31 (29, 34)
BMI Pre-stroke*	26.35 (22.57, 31.07)
Pre-stroke mRS 0-2	72 (72)

Characteristic	
Comorbidities	
Hypertension	60 (59)
Peripheral vascular disease	5 (5)
Coronary artery disease	7 (7)
Atrial fibrillation	20 (20)
Diabetes mellitus	28 (28)
Previous stroke	22 (22)
Dyslipidaemia	18 (18)
Chronic lung disease	10 (10)
Current smoker	20 (20)

*All are n (%) except *Median (IQR)*

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Adherence to allocated treatment

91% adherence overall
No significant difference between allocated groups
Main reason was participant declined

	Criteria (%)
GO	≥90
REVIEW	70-89
STOP	<70

	Adherence (%)
7-10 days	85
Weekly to 3 months	92
Discharge	92
3 months (inpatient)	100

	Adherence (%)
CH-MAN	94
CH-POW	84
TP-MAN	87
TP-POW	80

Safety

- n=19 Serious adverse events (SAEs) in 16 patients
- n=119 Adverse events (AEs) in 47 patients
- No differences in SAEs between allocated groups or sites

	Number (%) SAEs
Salford	8 (42)
Fairfield	2 (11)
Preston	5 (26)
Whiston	4 (21)

	Number (%) of SAEs	Number (%) participants with SAEs
CH-MAN	3 (16)	3 (19)
CH-POW	7 (37)	7 (44)
TP-MAN	3 (16)	2 (13)
TP-POW	6 (32)	4 (25)

SAE	n
Pneumonia/ sepsis	5
Other infection/ sepsis	3
COVID-19	1
Venous thromboembolism	2
Seizure	1
Neurological deterioration	
Massive intracranial haemorrhage	1
Hydrocephalus	1
Recurrent severe stroke	1
Deterioration to end of life care	2
Cardiac arrest	1
Syncopal episode	1

Collection of outcome measures

	Baseline	7-10 Days Follow up	Discharge	3 Months Follow Up - Inpatients	3 Months Follow Up - Outpatients	Overall
mRS	99%	N/A	92%	100%	88%	95%
THROAT	99%	83%	76%	N/A	N/A	86%
GOHAI	96%	81%	79%	N/A	N/A	85%
EQ5D5L - Index	N/A	N/A	75%	75%	N/A	75%
EQ5D5L - VAS	N/A	N/A	71%	75%	N/A	73%

mRS was collected in ≥80%
THROAT and GOHAI also generally ≥80%

Data collection at the discharge timepoint and EQ5D5L less complete

Criteria (%)	
GO	≥80
REVIEW	65-79
STOP	<65

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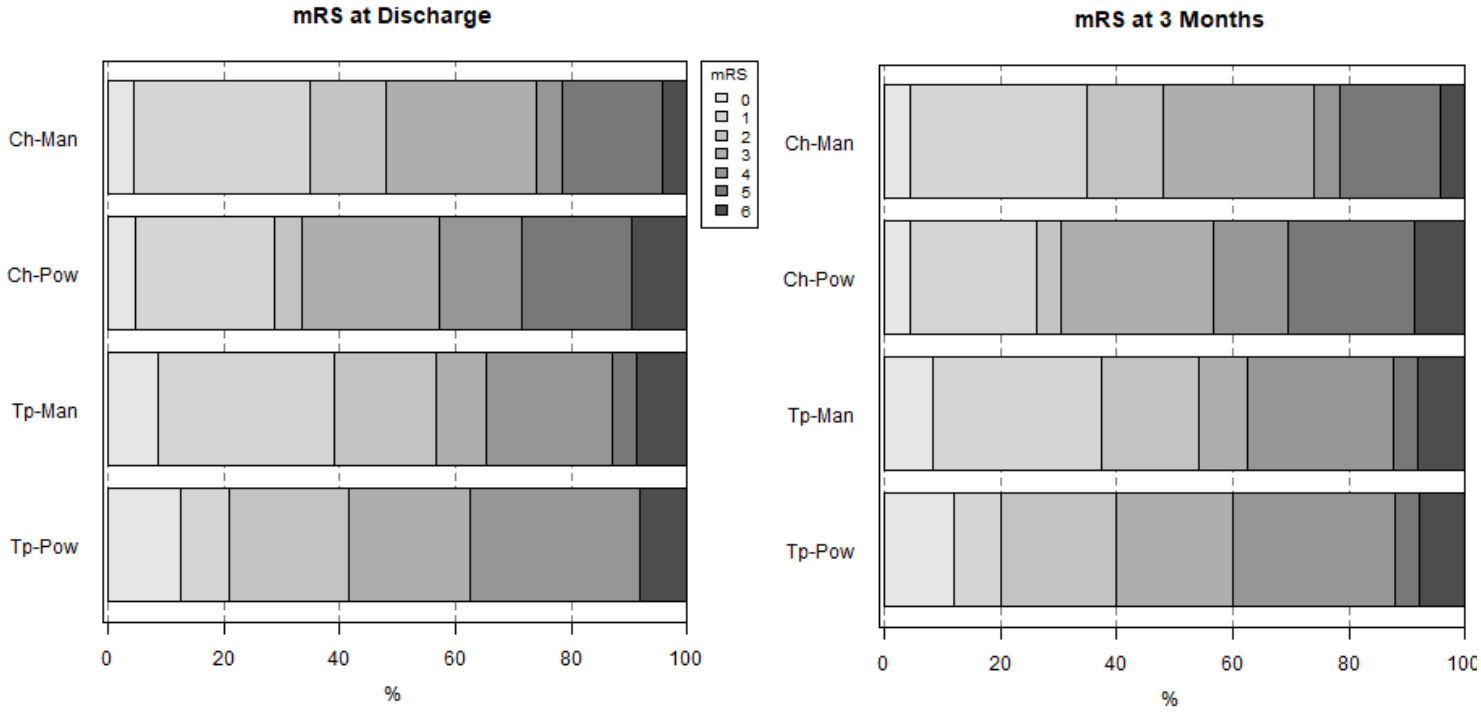
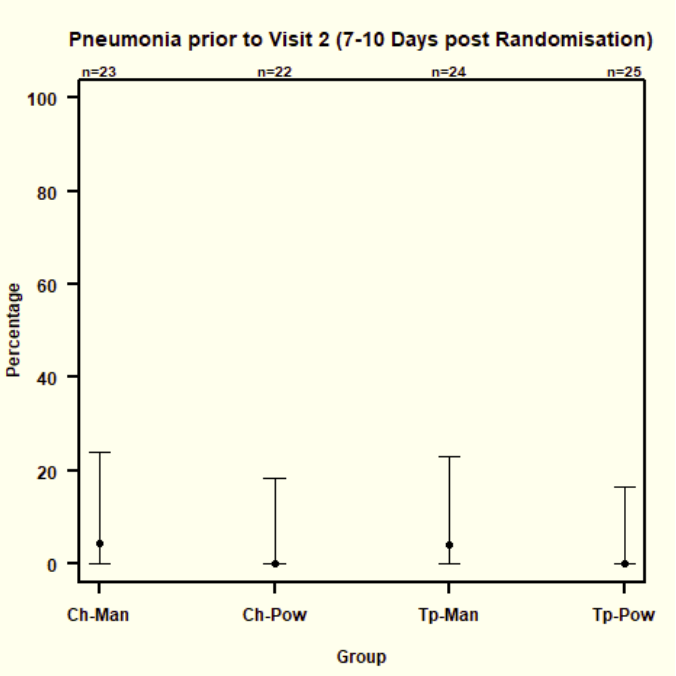
Exploratory secondary outcomes: mRS

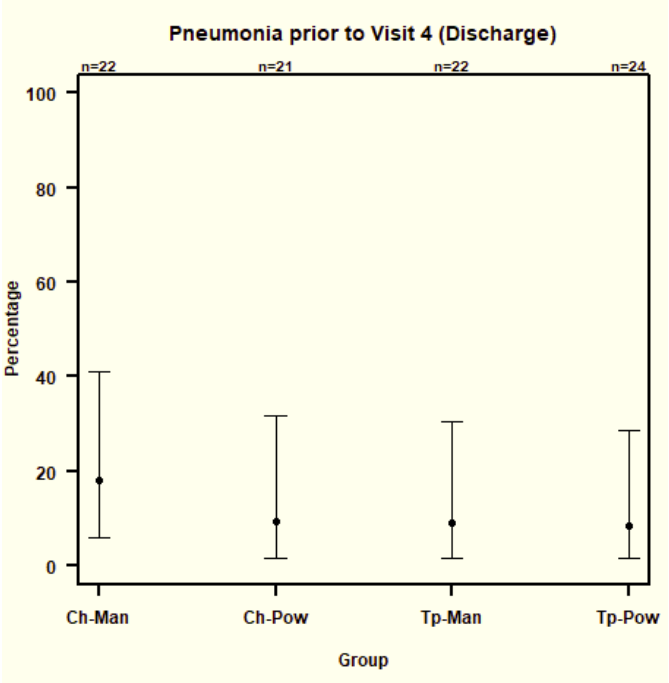
No significant difference in distribution of mRS between allocated treatment groups



Exploratory secondary outcomes: pneumonia

No significant difference in incident pneumonia between allocated treatment groups





Other exploratory secondary outcomes

No significant differences between allocated treatment groups

- THROAT
- GOHAI
- EQ5D5L

- ?LoS
- ?Discharge destination

Conclusions

- CHOSEN met *a priori* quantitative feasibility criteria
- No safety concerns
- No differences in any outcomes between allocated groups
- Further learning from process evaluation
- Definitive phase 3 multicentre trial required

Acknowledgements


Paul Brocklehurst


Wendy Westoby


Ian Clements


Liz Lightbody


Eileen Jones


Zoe Hoare


Andrew Brand


Fiona Sandom


Giles McCracken


Marian Brady


Peter Langhorne


Caroline Watkins

Clare Gross, Salford Royal Hospital, Northern Care Alliance
Catherine Davidson, UCLAN
Lucy Talbot, Whiston Hospital, St Helens and Knowsley Teaching Hospitals NHS Trust
Saravanan Narayanamoorthi, Fairfield General Hospital, Northern Care Alliance
Anu Thomas, Royal Preston Hospital, Lancashire Teaching Hospitals NHS Foundation Trust
Research practitioners/ nurses ward staff at the participating sites
The Trial Steering Committee and Data Monitoring Committee