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A randomised feasibility trial exploring management of benign paroxysmal positional vertigo in acute traumatic brain injury

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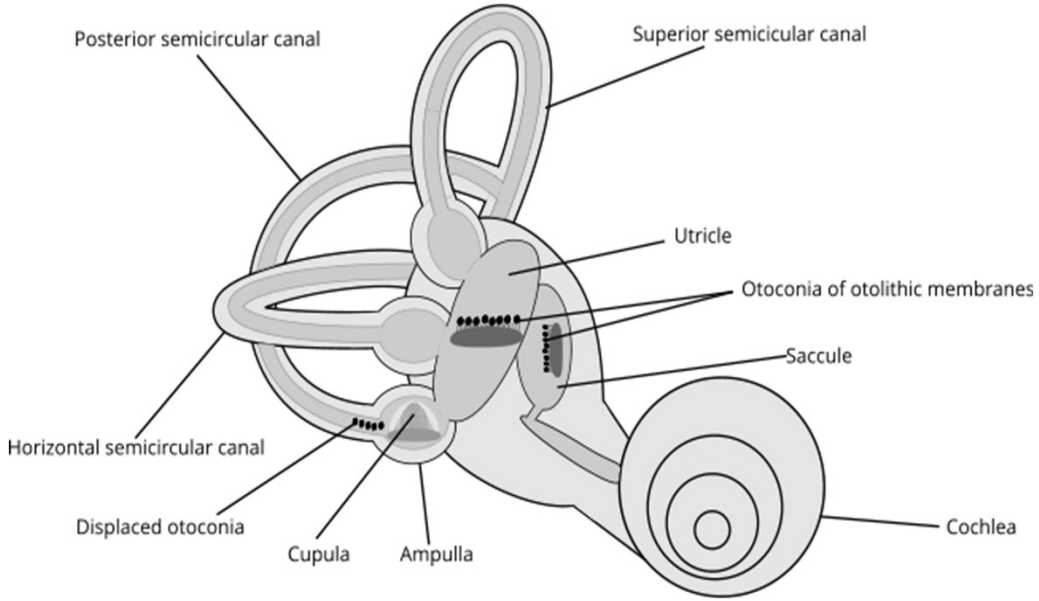
Rebecca Smith

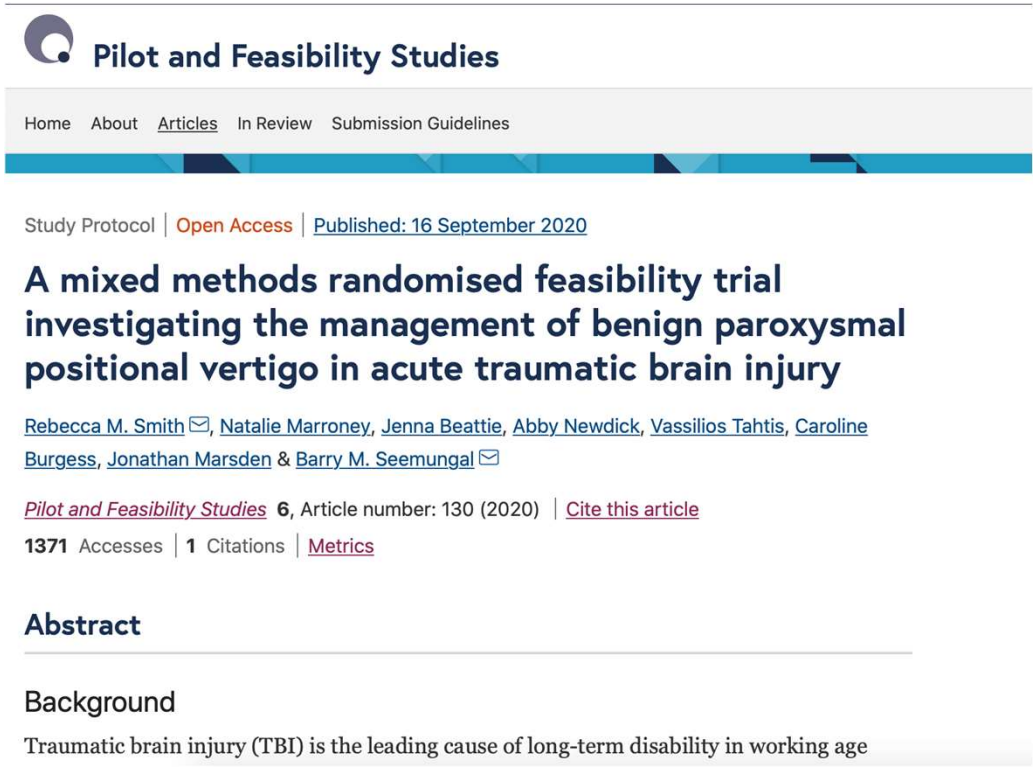
Imperial College London

Background and rationale

- Dizziness frequent in patients with acute traumatic brain injury (TBI)
- BPPV most common dizziness diagnosis in acute TBI



Feasibility Study….



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Study Protocol | Open Access | Published: 16 September 2020

A mixed methods randomised feasibility trial investigating the management of benign paroxysmal positional vertigo in acute traumatic brain injury

Rebecca M. Smith, Natalie Marroney, Jenna Beattie, Abby Newdick, Vassilios Tahtis, Caroline Burgess, Jonathan Marsden & Barry M. Seemungal

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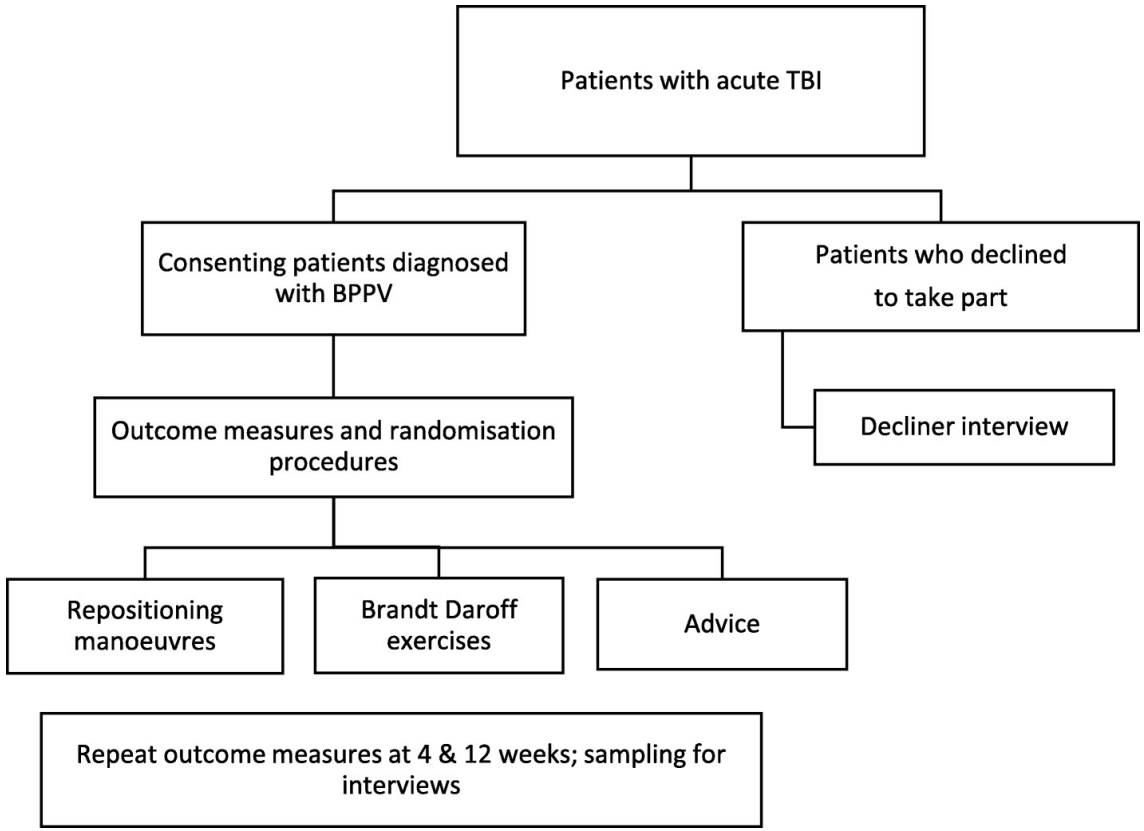
Abstract

Background

Traumatic brain injury (TBI) is the leading cause of long-term disability in working age

- Ascertain recruitment and retention
- **Explore acceptability of procedures and treatment**
- Identify any adverse events
- NOT treatment effectiveness

Methods



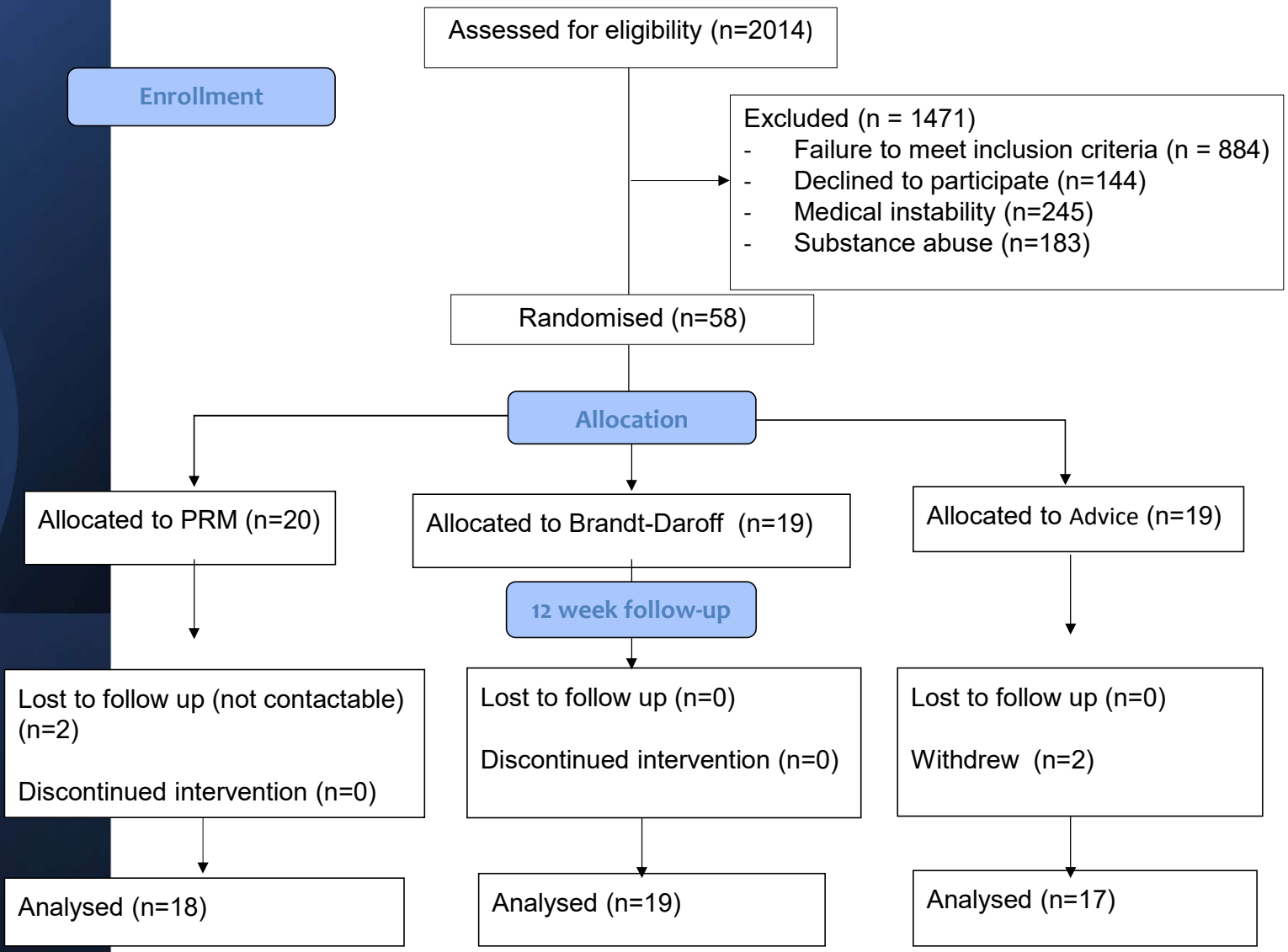
Inclusion:
- >18 years
- Inpatient on TBI ward

Three Major Trauma Centres
- St George's Hospital
- King's College Hospital
- St Mary's Hospital

- TBI as defined by Mayo severity scale

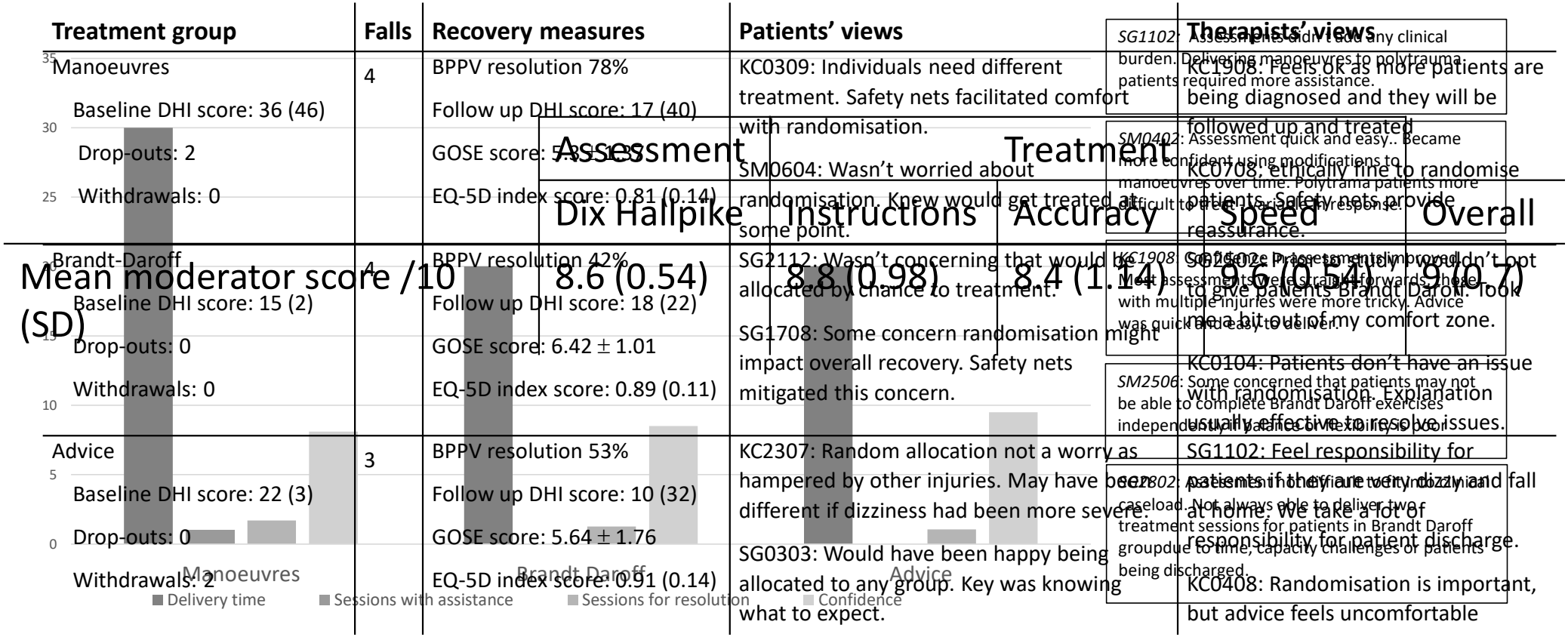
Exclusion:
- History of substance abuse
- Medical instability
- Cervical instability

Study flow diagram



Key feasibility findings

Treatment group	Falls	Recovery measures	Patients' views	Therapists' views
Manoeuvres Baseline DHI score: 36 (46) Drop-outs: 2 Withdrawals: 0	4	BPPV resolution 78% Follow up DHI score: 17 (40) GOSE score: 5.33 ± 1.65 EQ-5D index score: 0.81 (0.14)	KC0309: Individuals need different treatment. Safety nets facilitated comfort with randomisation. SM0604: Wasn't worried about randomisation. Knew would get treated at some point.	*SG1102*: Assessments didn't add any clinical burden. Delivering manoeuvres to polytrauma patients required more assistance. *SM0402*: Assessment quick and easy.. Became more confident using modifications to manoeuvres over time. Polytrama patients more difficult to treat. Variable early response.
Brandt-Daroff Baseline DHI score: 15 (2) Drop-outs: 0 Withdrawals: 0	4	BPPV resolution 42% Follow up DHI score: 18 (22) GOSE score: 6.42 ± 1.01 EQ-5D index score: 0.89 (0.11)	SG2112: Wasn't concerning that would be allocated by chance to treatment. SG1708: Some concern randomisation might impact overall recovery. Safety nets mitigated this concern.	*KC1908*: Assessments improved confidence. Most assessments were straightforwards, those with multiple injuries were more tricky. Advice was quick and easy to deliver. *SM2506*: Some concerned that patients may not be able to complete Brandt Daroff exercises independently if balance or flexibility is poor.
Advice Baseline DHI score: 22 (3) Drop-outs: 0 Withdrawals: 2	3	BPPV resolution 53% Follow up DHI score: 10 (32) GOSE score: 5.64 ± 1.76 EQ-5D index score: 0.91 (0.14)	KC2307: Random allocation not a worry as hampered by other injuries. May have been different if dizziness had been more severe. SG0303: Would have been happy being allocated to any group. Key was knowing what to expect.	*SM2802*: Assessments fine but very time consuming as caseload. Not always able to deliver two treatment sessions for patients in Brandt Daroff groupdue to time, capacity challenges or patients being discharged.



Therapists' views

KC1908: Feels ok as more patients are being diagnosed and they will be followed up and treated

KC0708: ethically fine to randomise patients. Safety nets provide reassurance.

SG1202: Assessments didn't add much but I got a bit out of my comfort zone.

KC0104: Patients don't have an issue with randomisation. Explanation usually effective to resolve issues.

SG1102: Feel responsibility for patients if they are very dizzy and fall at home. We take a lot of responsibility for patient discharge.

KC0408: Randomisation is important, but advice feels uncomfortable

Trial progression criteria

Objective	**Success criteria**	**Feasibility study data and considerations**	**Stop, think, or go?**
Establish proportion of sample eligible	60% of screened patients eligible	Data: 27% of those screened were eligible *Considerations: Large numbers were excluded. Screening difficulties noted*	**Think** Inclusion criteria need more definition
Explore consent rate	Initially 30%; rising to 50% of eligible patients consenting	Data: 34% of those eligible were consented *Considerations: Content and delivery method of study information could be modified*	**Go** Consider modifying patient information
Investigate dropout rate	≤ 40% drop out rate	Data: A dropout rate of 7% was observed. *Considerations: 50% of dropouts were withdrawals were from the advice group*	**Go** Consider a different trial design

Conclusions and reflections

Therapist led management of BPPV is safe, acceptable and feasible

Potential to progress towards a more definitive RCT

Value of qualitative methodology in early trials

Value of integrating qualitative and quantitative findings during analysis

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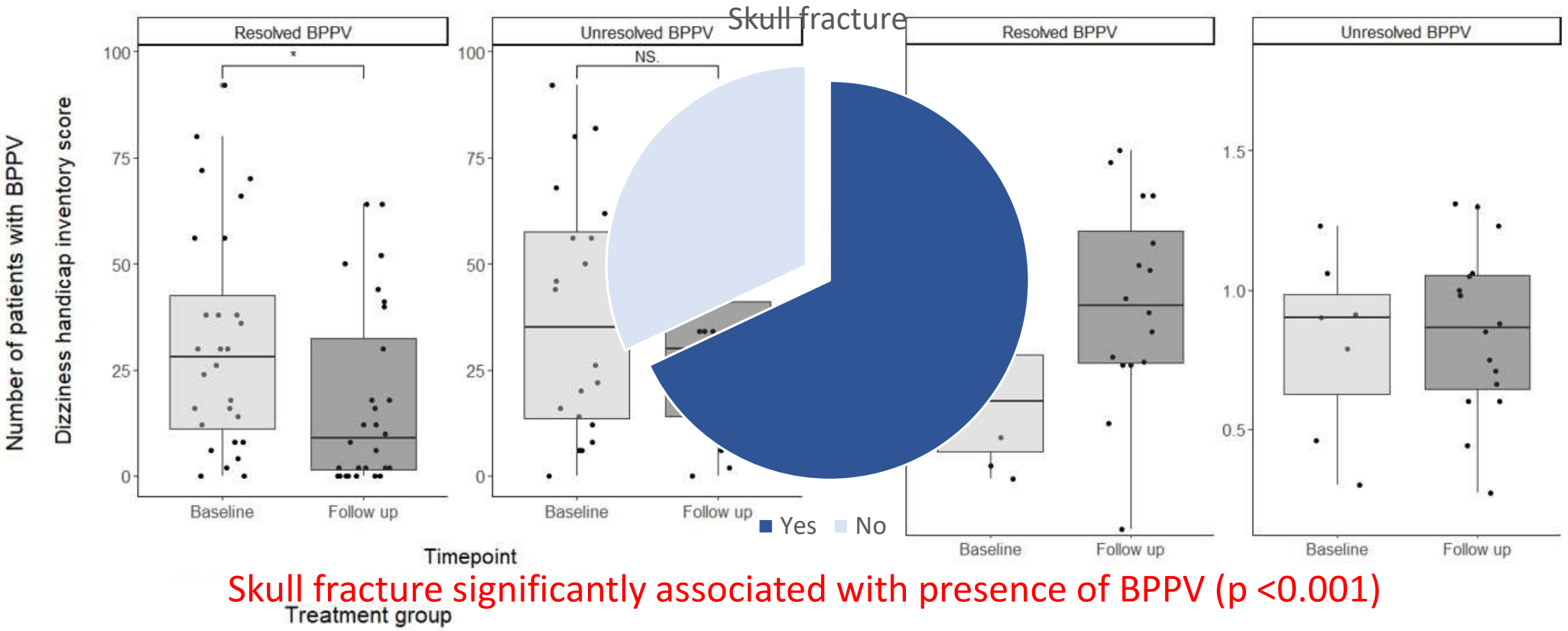
Clinical findings



Skull fracture significantly associated with presence of BPPV ($p < 0.001$)