



Patient and public involvement as part of the 'ENPENS' research trial.

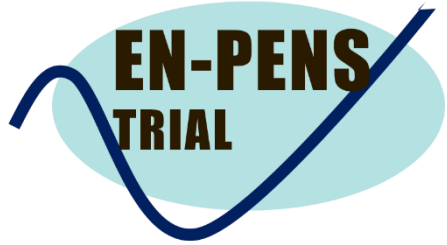
**Selina Johnson**

PI ENPENS trial.

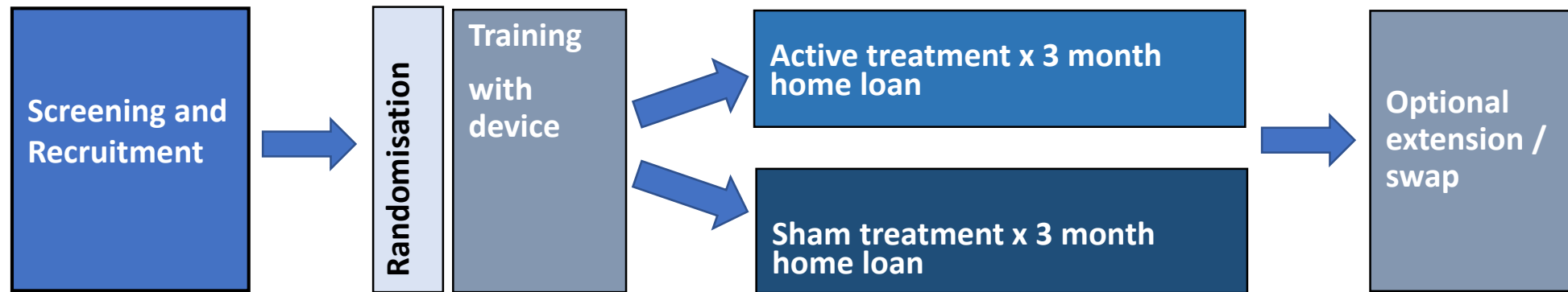
Pain Specialist Physio @ The Walton Centre, Liverpool.

Part- Time PhD student @ University of Liverpool

Focus on Pain research Day 2020.



A randomised patient-assessor blinded sham controlled trial of External non-invasive peripheral nerve stimulation for chronic neuropathic pain following peripheral nerve injury.



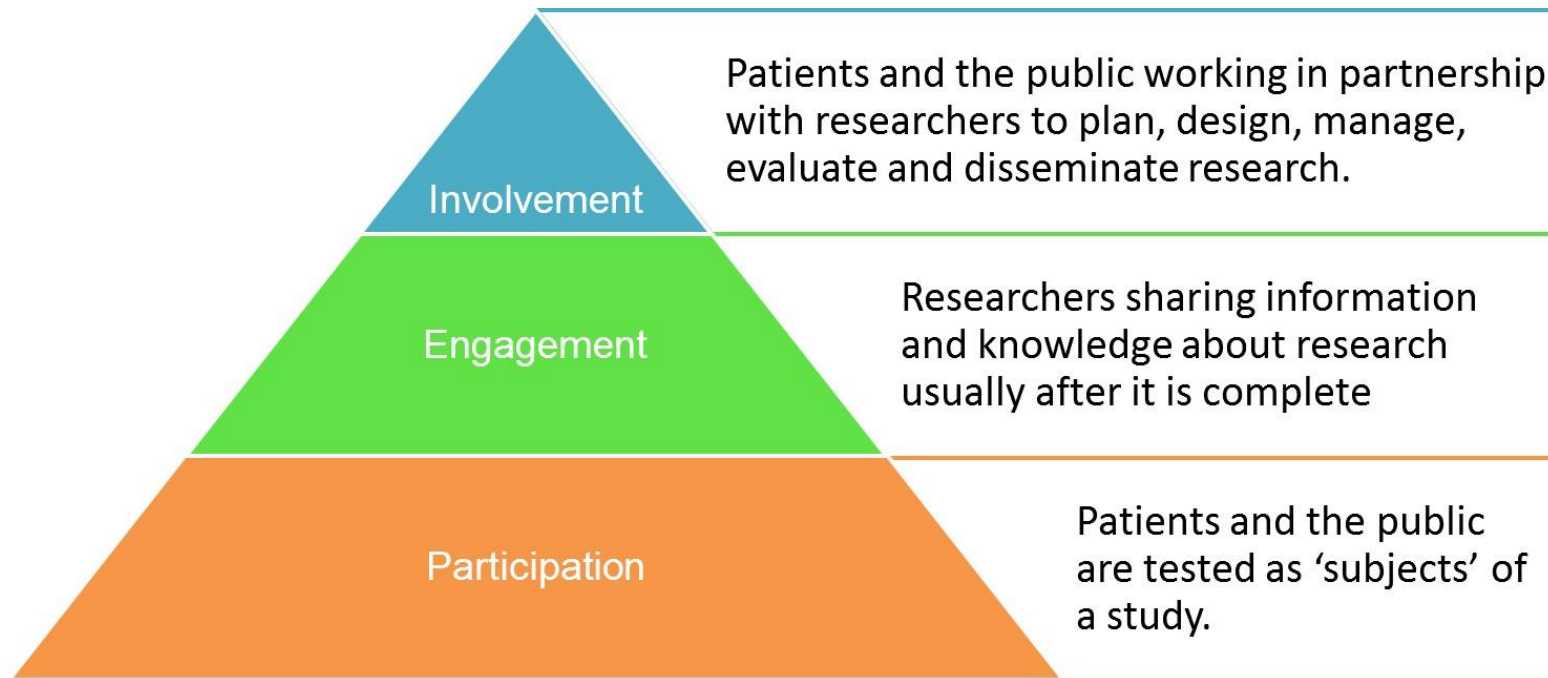
**Funded by a NIHR RfPB grant**

Primary aim:

- Establish whether EN-PNS is effective in reducing pain intensity for persons with chronic neuropathic pain following peripheral nerve injury (PPNI) after 3 months of treatment as compared to sham treatment.
- We have currently completed recruitment and analysis data



- PPI is a strong requirement for the RfPB grant funding stream.
- The majority of funding streams require researchers to show PPI. Where users have not been involved, researchers must show clear justification for not including them.
- *“Patient and Public Involvement (PPI) means actively working in partnership with patients and members of the public to plan, manage, design and carry out research” INVOLVE*



Members of the public can have a role in health / care research in three broad levels.



# EN-PENS TRIAL

Plan/ Design

Manage/ Conduct

Disseminate

# Plan/ Design

Audit provided  
proof of concept  
Before ENPENS  
study



*“ENPENS should have been offered sooner in relation to their pain management”*

*‘endorsed the need for evidence to support its use within the NHS.’*

Identify and prioritise research topic

# Research Design Service

Public Involvement fund  
£350



## Presented outline study proposal to group

- Viewed establishing treatment efficacy as a primary aim,
  - Endorsed the study as ‘worthwhile’
  - Strength treatment could be self-administered.
- 
- **Methodological changes:**
    - Exclusion of a third comparator arm using TENS
    - Reduction of treatment period
    - Weekly telephone review
    - Prioritised outcome measures and methods of outcome collection to ensure they captured ‘meaningful’ change in respect to the study population.





Tested Sham



Evaluated questionnaires and  
all patient materials





# Manage/ Conduct

## TMG

Day-to-day trial management

## TSG

Supervision MRC GCP guidelines.

### What PPI gives:

- Provide public viewpoint throughout the study
- Management/ conduct
- Reviewed protocol, all study paperwork, processes.
- Aid recruitment, retention via own knowledge and experience.

### What PPI should get:

- Travel costs
- Support for PPI members (INVOLVE/ The Walton Centre Patient Carer Public Involvement and Engagement Strategy Committee (PPIESC)).

# Further considerations during the study

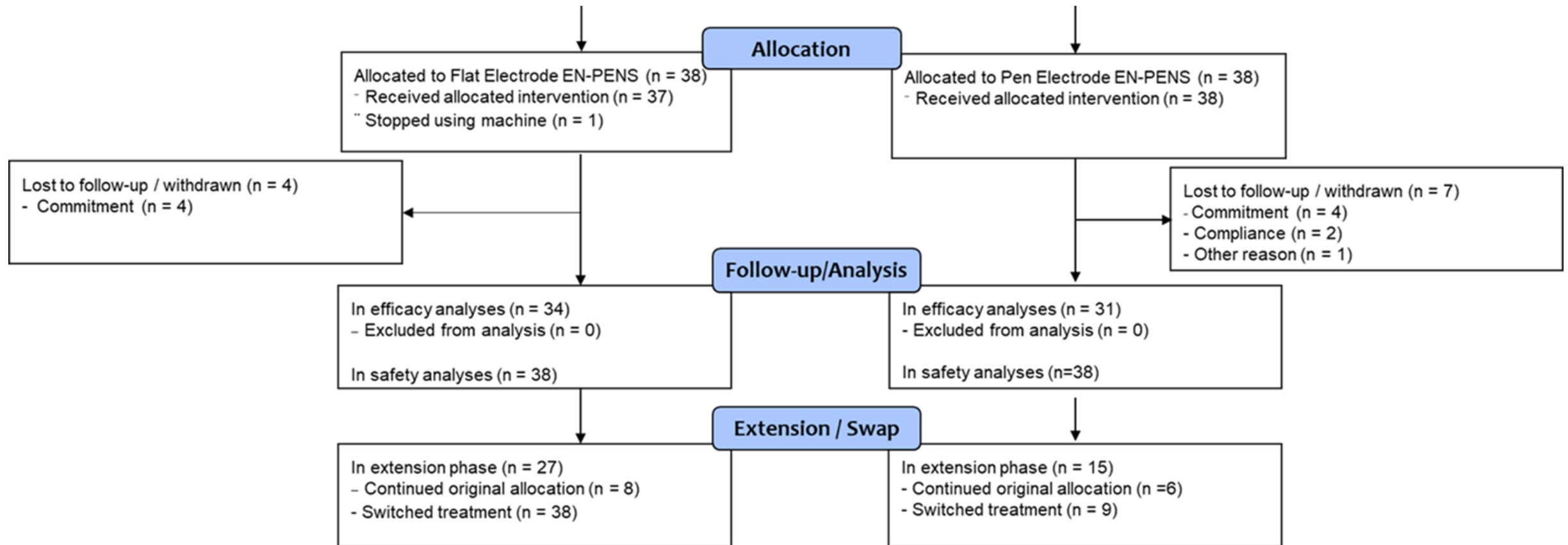
- Taxi in and flexibility in appointment times
- Agree time for telephone reviews
- Support groups to advertise the study
- Northwest coast research community lead



**All helped in respect to optimising retention and recruitment pre-study and during study**

# Successes

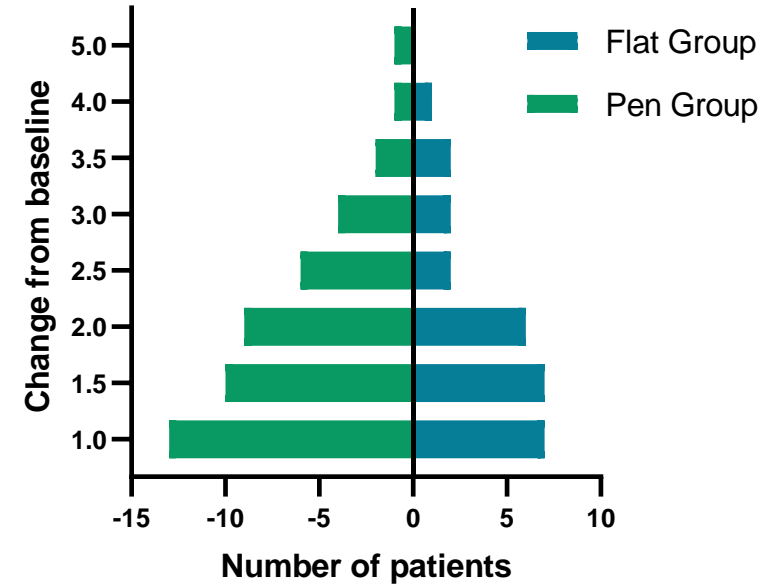
- Recruitment to target 76 patients



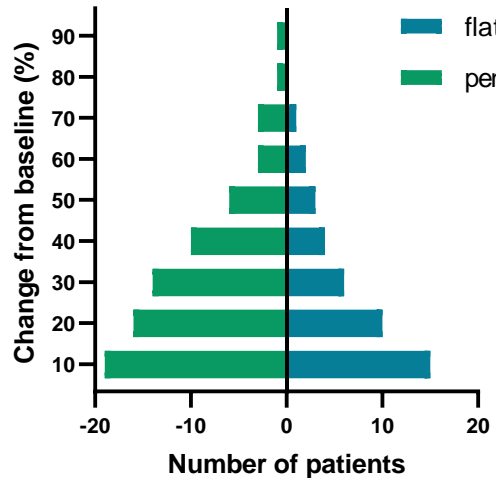
# Disseminate

- Canvas patient opinion/ focus group
- Newsletter to patients feeding back study
- Review and contribute to final report and write up of study.
- Advise on different ways of disseminating information.

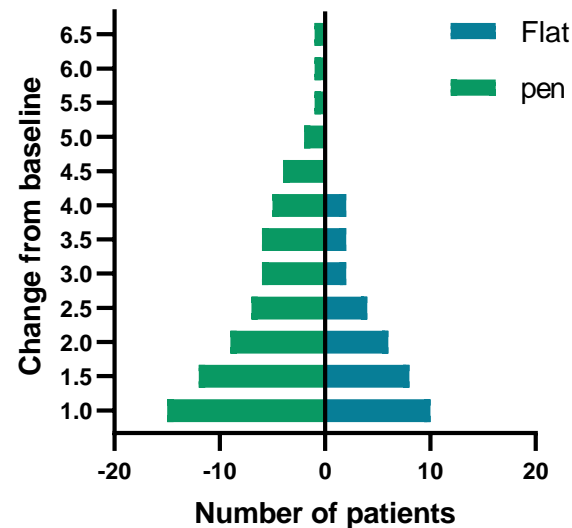
### Average Pain



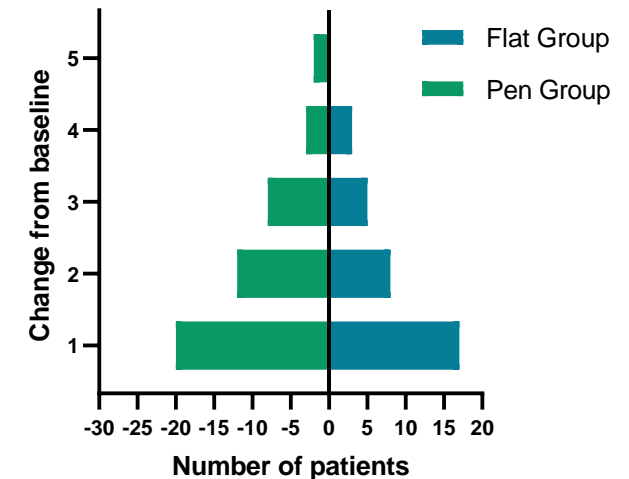
### SA of Allodynia



### BPI interference



### Worst Pain



What could we  
have done  
better?

- TSG/TMG further support
- Ensured PPI connected to other groups/contacts.
- Consider further debriefing.
- Enhancing information about trial to support adherence- pre-trial information sessions
- Social media
- Record and evaluate our PPI involvement

# Conclusions

- PPI important but need to ensure not just lip service
- Involving the right people makes a big difference!
- Improve the quality and relevance of research.
- Help with design of key study aspects
- Ensure research is user friendly and don't hit as many stumbling blocks
- Lived experience with condition and patient pathways – Invaluable Knowledge resource
- Most research is funded by public monies and therefore research should involve the public



# Further information

NIHR PPI pages:

<https://www.nihr.ac.uk/patients-and-public/>

INVOLVE <http://www.invo.org.uk>

INVOLVES briefing notes on how to involve the public in research

<http://www.invo.org.uk/resource-centre/resource-for-researchers/>

<https://www.invo.org.uk/posttypepublication/public-involvement-in-clinical-trials/>

# References

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## Research Team

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