

THE AWARENESS STUDY: **AN UPDATE**

Renae Gamble
N-CRESS – Austin Health

Friday 20th October
MSNA 2023

RESEARCH TEAM

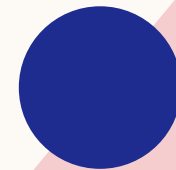
Melanie McMurtrie

Joanne Dimovitis

Belinda Bardsley

Renae Gamble

Elise Heriot





BACKGROUND

Combination of two ideas:

1. Local quality improvement project (QIP)
2. Participation in nurse-led research

THE AWARENESS STUDY



OBJECTIVES

Our **primary purpose** is to improve service delivery & patient outcomes whilst understanding motivation to participate in clinical trials.

A **secondary goal** is to inform others of our findings to promote further work in service quality improvement

WHY?



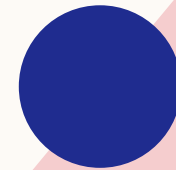
RATIONALE

- Enhanced understanding of subjective motivation & lived experience
- Safeguard future involvement in research
- Improve overall patient experience & outcomes
- Improved service delivery

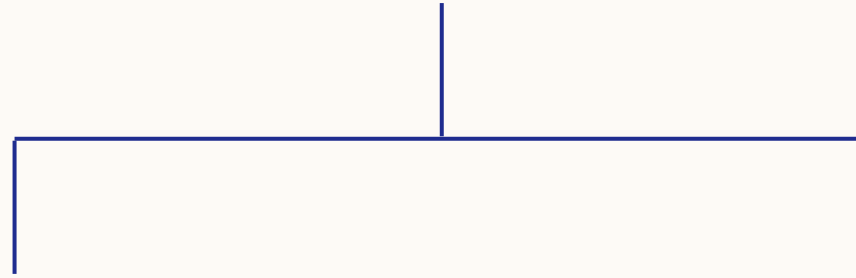
THE AWARENESS STUDY:

A REVIEW OF CLINICAL TRIALS SERVICE DELIVERY AT N-CRESS

✓ Non-HREC ethics approval
3rd April 2023



PATIENT GROUPS



GROUP 1: CLINICAL GROUP *60 PARTICIPANTS*

Inclusion Criteria:

- Diagnosis of MS
- Attends Neuroimmunology clinic
- Attended clinic on ≥ 2 consecutive appts

Exclusion Criteria:

- Diagnosis other than MS
- ≥ 2 non-attendance at clinic or cancellations

GROUP 2: TRIAL PARTICIPANTS *30 PARTICIPANTS*

Inclusion Criteria:

- Current or recent (≤ 12 months) of a CT within N-CRESS
- Attended regular study visits APP
- Attended clinic on ≥ 2 consecutive appts

Exclusion Criteria:

- ≥ 2 non-attendance at clinic or cancellations

FEEDBACK FORMS

Clinical Trial Feedback Form

As a current or recent past clinical trial participant at N-CRESS, we would like to ask for your feedback so that we can understand why you chose to take part in a clinical trial, and how you found this experience.

We would like your feedback in order to improve our clinical trials program in the future.

1. Type of clinical trial – please tick the relevant box.

- ☐ Multiple Sclerosis (MS)
☐ Other (see below)

Please specify: _____

2. Reason for Trial Participation – please circle your response.

	Strongly disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
I participated in a clinical trial because of the possibility of personal benefit	1	2	3	4	5	6	7
I participated in a clinical trial because I wanted to contribute to medicine/science	1	2	3	4	5	6	7
I participated in a clinical trial due to a lack of other available treatment options	1	2	3	4	5	6	7
I participated in a clinical trial due to a desire to help people with my disease/condition in the future	1	2	3	4	5	6	7

3. Please select your highest motivation factor for trial participation – please tick your response (one only)

- ☐ Possibility of personal benefit
☐ Contribution to medicine/science
☐ Lack of other options available
☐ Desire to help others with my disease/condition in the future

4. Are there any additional reasons you participated in a clinical trial that are not listed above?

5. Consent, Communication and Support – please circle your response

	Strongly disagree	Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Agree	Strongly Agree
The initial process of informing me about the study and what my participation involved was adequate	1	2	3	4	5	6	7
I was given the opportunity to ask questions relating to the study	1	2	3	4	5	6	7
I had adequate time to read, consider and discuss the information and informed consent form provided	1	2	3	4	5	6	7
I felt comfortable about providing written consent	1	2	3	4	5	6	7
I was kept well informed by my study team throughout the clinical study	1	2	3	4	5	6	7
Any issues I had were followed up promptly and thoroughly by my study team	1	2	3	4	5	6	7
The print information provided to me was in language that I understand	1	2	3	4	5	6	7
I felt supported by the study team	1	2	3	4	5	6	7

Additional comments:



RESEARCH QUESTIONS

1. What patient feedback differences exist between the N-CRESS “routine care” patient group & participants of MS clinical trials?
2. What motivates people with MS to participate in clinical trials?
3. What are the lived experience insights from participants of clinical trials?
4. Does anything need to change in our service delivery to improve the experience for patients & participants?
5. Can these findings be extrapolated to share the results with other MS centers?

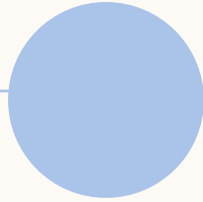


PRELIMINARY RESULTS

RESEARCH QUESTION #1

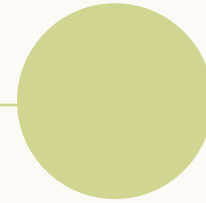
What patient differences exist between the N-CRESS “routine care” patient group & participants of MS clinical trials?

DIRECT COMPARISON



GROUP 1: CLINICAL GROUP

- 25% males & 75% females
- 58% aged between 18-49
- 78% agree that they are involved in decision making
- 95% are satisfied with overall experience



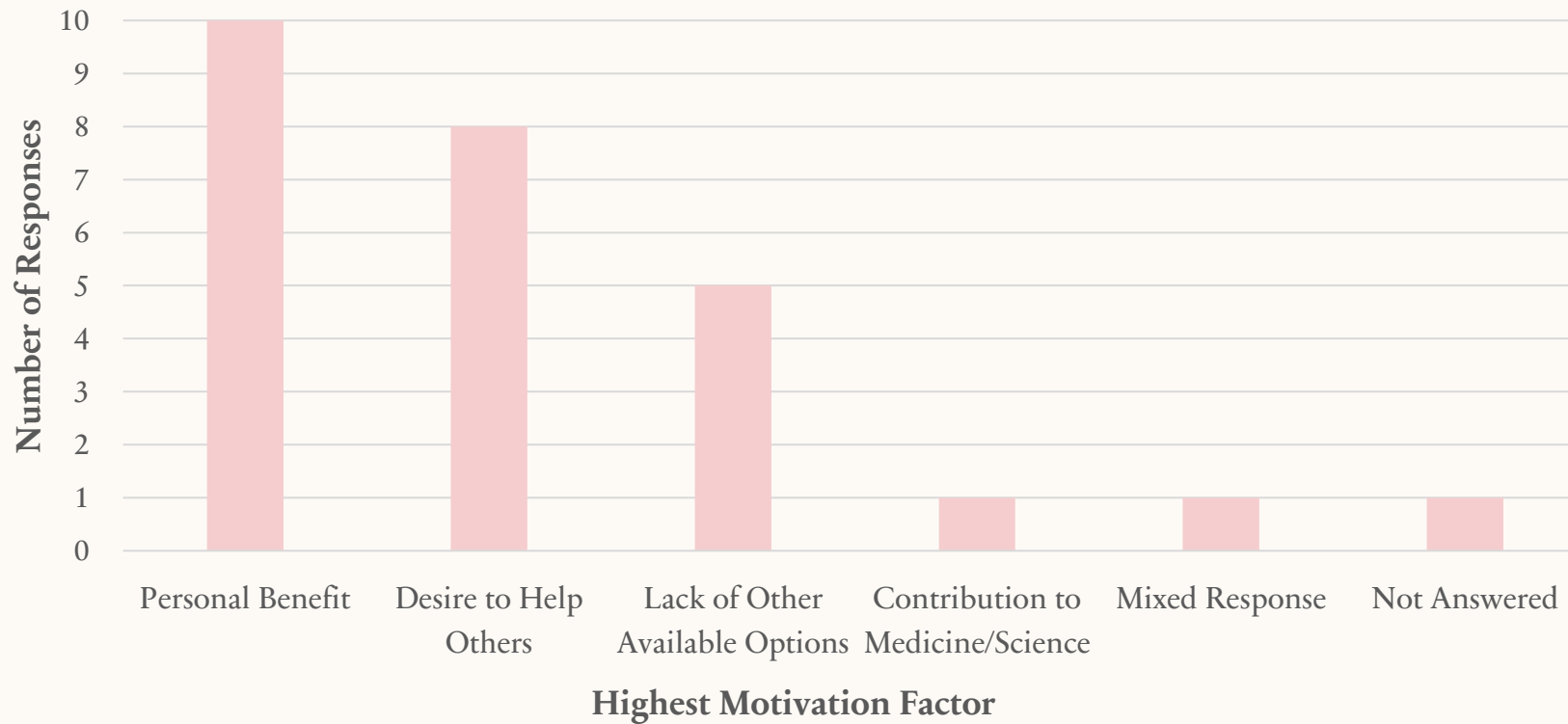
GROUP 2: TRIAL PARTICIPANTS

- 36% males & 64% females
- 44% aged between 18-49
- 96% agree that they are involved in decision making
- 96% are satisfied with overall experience

RESEARCH QUESTION #2

What motivates people with MS to participate in clinical trials?

MOTIVATION



Available responses at time of analysis = 25

RESEARCH QUESTION #3

What are the lived experience insights from participants in clinical trials?

LIVED EXPERIENCE: CONSENT

Statement	Strongly Agree or Agree
The initial process informing me about the study & what my participation involved was adequate	88%
I was given the opportunity to ask questions relating to the study	96%
I had adequate time to read, consider & discuss the information & informed consent provided	96%
I felt comfortable providing informed consent	88%

RESEARCH QUESTION #3

What are the lived experience insights from participants in clinical trials?

LIVED EXPERIENCE: COMMUNICATION & SUPPORT

88%

Agreed that any issues
they had were
followed up promptly
& thoroughly

88%

Agreed that they felt
supported by the
study team

88%

Agreed that they were
kept well informed
throughout the
clinical study

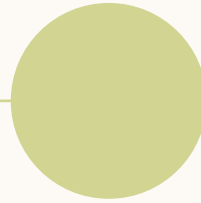
88%

Agreed that the print
information provided
was in a language they
understood

RESEARCH QUESTION #3

What are the lived experience insights from participants in clinical trials?

LIVED EXPERIENCE: COMMUNICATION & SUPPORT

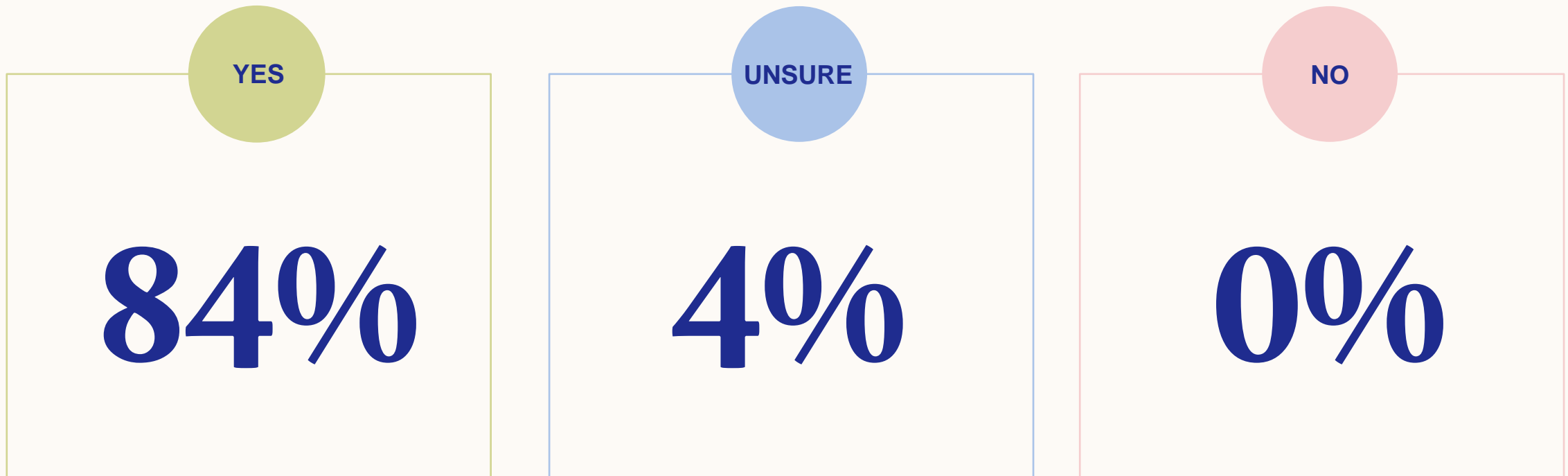


- “I would be lost without this service. The N-CRESS team have helped me better understand, manage & cope with my illness & are wonderful & easy to talk to.”
- “Sometimes things could be made a little clearer for someone that is not in the medical field.”
- “Excellent service by doctors & nurses. I was provided with a great team.”
- “Send appointment reminders – SMS.”
- “A huge shoutout to all the staff – from reception to the doctors. They are all a credit to the unit!”

RESEARCH QUESTION #3

What are the lived experience insights from participants in clinical trials?

WOULD YOU PARTICIPATE IN A CLINICAL TRIAL IN THE FUTURE?



*3 unanswered responses

RESEARCH QUESTION #5

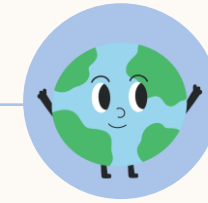
Can these findings be extrapolated to share the results with other MS centers?

FUTURE PLANS



INTERNAL

- Finalisation of data & report
- Part of an internal service review to inform future care & support
- In-house quality improvement projects (QIPs)



EXTERNAL

- Presentation of final project both nationally & internationally
- Publication of results
- Potential for a larger scale MS nurse-led project in Australia & New Zealand

REFERENCES

- Lantos, J. D. (1999). The “inclusion benefit” in clinical trials. *The Journal of Pediatrics*, 134(2), 130-131. doi: 10.1016/s0022-3476(99)70400-2
- McNicholas, N., Patel, A., & Chataway, J. (2012). It is better to be in a clinical trial than not: Lessons learnt from clinical neurology—the management of Acute Multiple Sclerosis relapses. *QJM*, 105(8), 775–780. doi:10.1093/qjmed/hcs070
- Fernandes, N., Bryant, D., Griffith, L., El-Rabbany, M., Fernandes, N. M., Kean, C., ... Bhatnagar, N. (2014). Outcomes for patients with the same disease treated inside and outside of randomized trials: A systematic review and meta-analysis. *Canadian Medical Association Journal*, 186(16). doi:10.1503/cmaj.131693
- Multiple Sclerosis Australia. (2023). Retrieved from <https://www.msaustralia.org.au/what-is-multiple-sclerosis-ms/>
- Genesis Research Services. (2023). Retrieved from <https://genesishresearchservices.com/product/good-clinical-practice-ich-gcp-course/>

THANK YOU 😊

Renae Gamble
Immunotherapy & Research Nurse
N-CRESS – Austin Health

renae.gamble@austin.org.au

Friday 20th October
MSNA 2023