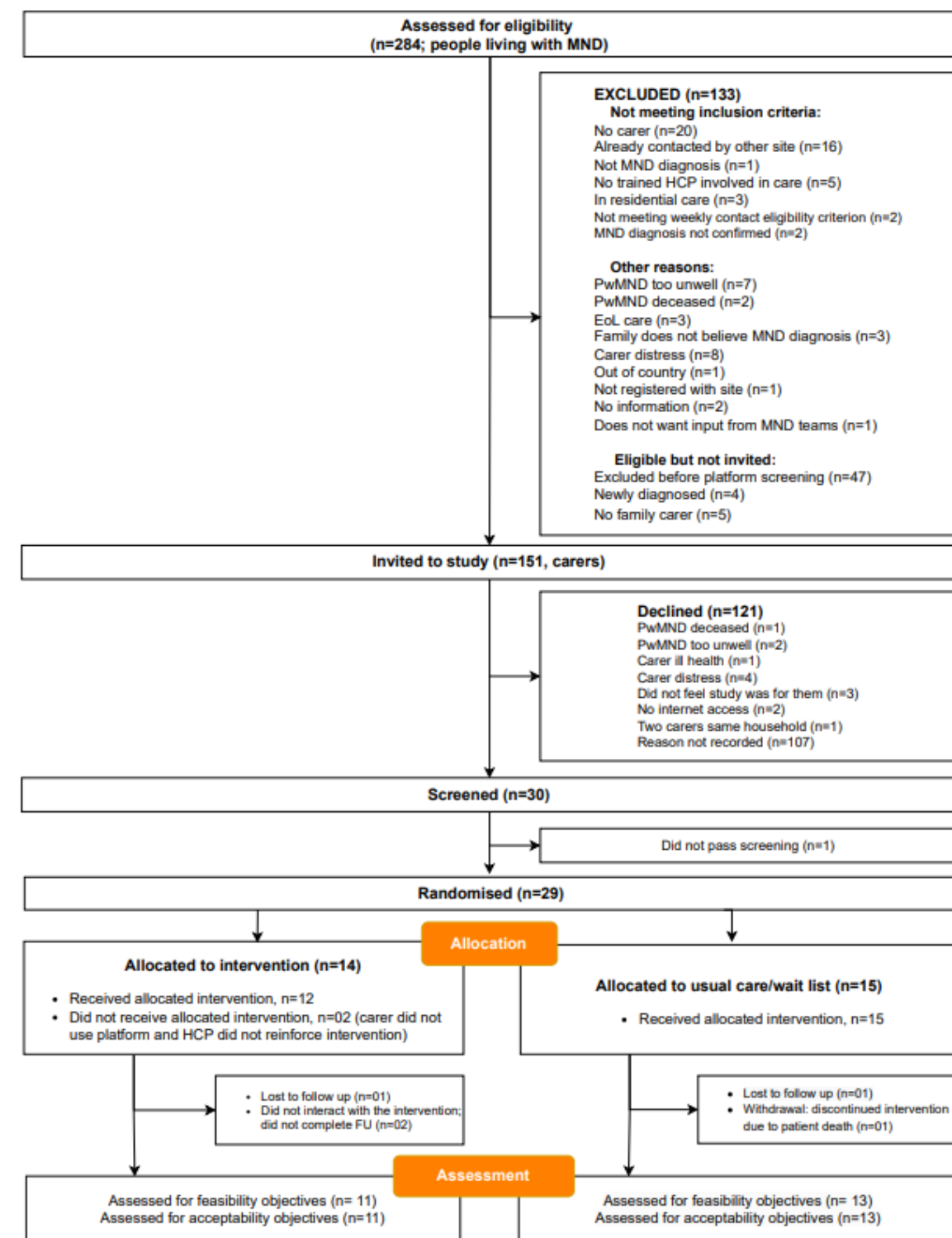


PRACTICAL MANAGEMENT OF BEHAVIOURAL IMPAIRMENT IN MOTOR NEURONE DISEASE: MINDTOOLKIT FEASIBILITY STUDY

SUMMARY OF RESULTS

PARTICIPANT FLOW



BASELINE CHARACTERISTICS

Table 1: Baseline Descriptive Statistics of people with MND who were supported by the carer in the MiNDToolkit Study

	Intervention group (n=14)	Control group (n=15)	Overall (n=29)
Age of person with MND: median (IQR)	65 (61, 72)	67 (59, 75)	66 (61, 72)
Gender, male: n (%)	10 (71.4%)s	10 (66.7%)	20 (69.0%)
MND diagnosis as reported by carer: n (%)	6 (42.9%)	6 (40.0%)	12 (41.4%)
ALS	2 (14.3%)	4 (26.7%)	6 (20.7%)
Bulbar onset MND/Progressive bulbar palsy	3 (21.4%)	0	3 (10.3%)
Dementia	3 (21.4%)	1 (6.7%)	4 (13.8%)
Primary lateral sclerosis	0	1 (6.7%)	1 (3.5%)
Progressive muscular atrophy	2 (14.3%)	4 (26.7%)	6 (20.7%)
Not sure			
Employment status: n (%)			
Full-time	0	1 (6.7%)	1 (3.5%)
Part-time	1 (7.1%)	0	1 (3.5%)
Not working	3 (21.4%)	4 (26.7%)	7 (24.1%)
Retired	10 (71.4%)	10 (66.7%)	20 (69.0%)

OUTCOME MEASURES

Table 2. MiNDToolkit feasibility trial: Carer Questionnaire outcome descriptive statistics at Baseline (n=29) and Follow-up (n=24)

	Intervention group		Control group		Overall	
	Baseline (n=14)	Follow-up (n=11)	Baseline (n=15)	Follow-up (n=13)	Baseline (n=29)	Follow-up (n=24)
GAD total score: median (IQR)	7.0 (4.0, 8.0)	7.0 (4.0, 11.0)	5.0 (2.0, 7.0)	4.5 (3.0, 6.5) ^a	6.0 (3.0, 8.0)	5.0 (4.0, 10.0) ^a
<i>Higher scores denote greater anxiety</i>						
CES total score: median (IQR)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)	10.0 (9.0, 11.0)	10.5 (9.5, 11.0) ^a	11.0 (9.0, 13.0)	11.0 (10.0, 13.0) ^a
<i>Lower scores denote better carer quality of life</i>						
PHQ-9 total score: median (IQR)	7.0 (3.0, 10.0)	9.0 (5.0, 11.0)	4.0 (3.0, 8.0)	5.0 (3.0, 12.0)	6.0 (3.0, 9.0)	7.5 (3.5, 11.5)
<i>Higher scores denote greater depressive symptoms</i>						
ICECAP-A tariff score: median (IQR)	0.66 (0.44, 0.92)	0.64 (0.44, 0.83)	0.78 (0.66, 0.89)	0.75 (0.64, 0.87) ^a	0.76 (0.61, 0.89)	0.73 (0.57, 0.83) ^a
<i>Tariff closer to 1 reflect better quality of life^b</i>						
About the person with ALS						
MIND-B^c: median (IQR)						
Disinhibition (transformed %)	78.1 (56.3, 87.5)	68.8 (37.5, 81.3)	81.3 (75.0, 93.8)	87.5 (75.0, 93.8)	81.3 (68.8, 93.8)	81.3 (59.4, 93.8)
Apathy (transformed %)	66.7 (50.0, 83.3)	50.0 (33.3, 66.7)	83.3 (50.0, 91.7)	83.3 (50.0, 91.7)	75.0 (50.0, 91.7)	58.3 (33.3, 83.3)
Stereotypical behaviour (transformed %)	68.8 (37.5, 87.5)	50.0 (37.5, 75.0)	87.5 (62.5, 100.0)	87.5 (62.5, 100.0)	75.0 (50.0, 100.0)	68.8 (43.8, 93.8)
Total raw score (max 36)	26.5 (17.0, 29.0)	23.0 (15.0, 24.0)	31.0 (26.0, 34.0)	30.0 (26.0, 34.0)	28.0 (23.0, 33.0)	25.0 (19.0, 31.0)
ALSFRS-R total score: median (IQR)	31.0 (26.0, 35.0)	27.0 (16.0, 32.0)	26.0 (18.0, 35.0)	23.0 (17.0, 34.0)	27.0 (21.0, 35.0)	25.0 (16.5, 33.0)

^a 1 participant missing (control group, follow-up) due to incomplete data.

^b ICECAP-A to a capability value between “0” and “1,” where no capability=0, to full capability=1.

^c For MiND-B disinhibition, apathy and stereotypical behaviour subscores, higher scores denote more marked behavioural symptoms. Subscores were transformed to percentages to allow for comparison between subscores, as each subscore has a different maximum raw score. For MiND-B total score, lower raw scores reflect more severe behavioural symptoms. Cut off is ≤ 32/36.

Table 3. MiNDToolkit feasibility trial: Analysis results of questionnaire outcomes at follow-up, using a generalised linear model.

Model outcome at follow-up ^a	Intervention group Mean (SD)	Control group Mean (SD)	Untransformed		Transformed	
			Adjusted Difference (95% CI ^b)	p-value	Adjusted Difference (95% CI ^b)	p-value
GAD total score (n=23)^c	7.45 (4.68)	5.50 (4.52)	-0.07 (-1.69, 1.55)	0.928	0.987 (0.671, 1.452)	0.944
CES total score (n=23)	11.45 (2.34)	10.50 (1.93)	0.20 (-0.60, 1.00)	0.613		
PHQ-9 total score (n=24)^c	8.82 (5.27)	7.38 (6.65)	-0.06 (-2.42, 2.30)	0.956	1.11 (0.85, 1.44)	0.421
ICECAP-A tariff score (n=23)^c	0.62 (0.24)	0.71 (0.23)	0.03 (-0.06, 0.11)	0.507	1.13 (0.84, 1.51)	0.393

^aGeneralised Linear model used, adjusted for baseline value of outcome variable where available, and treatment group.

^b95% Confidence Interval for parameter estimates.

^cTransformed models use a log transformation of the outcome. However, the PHQ-9, MIND-B apathy and ALSFRS models also use a reflection of the outcome before the log transformation, so the interpretation of the direction of score is reversed. The adjusted difference given for the transformed models is the geometric mean ratio (converted back to the original scale).

ADVERSE EVENTS

The risk of a serious adverse event arising from any of the research activities involved in this study is extremely low. Patients with MND about whom data is being anonymously collected are under the care of specialist clinics for their condition during the period of the study. The main focus of the study is on the health and wellbeing of the carer, and the intervention aims to provide psychoeducation and patient management suggestions to the carer rather than offering a clinical intervention to the person with MND.

As such, there were no adverse or serious adverse events reported for this study.