Preliminary Validation of the Distress Thermometer in People with Parkinson's Disease

Bronagh Reynolds, DClinPsy,[1,2] Susan O'Connell, DClinPsy[2,3] and Breda Cullen, PhD[1]*

[1] Institute of Health and Wellbeing, University of Glasgow, UK

[2] NHS Ayrshire and Arran, UK

[3] NHS Greater Glasgow and Clyde, UK

*Correspondence:

Dr Breda Cullen

Institute of Health and Wellbeing

University of Glasgow

1st floor, Administration Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow, G12 0XH, UK

Telephone: +44 (0)141 211 3912

Corresponding author email: Breda.Cullen@glasgow.ac.uk

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Summary

The Distress Thermometer (DT) has been validated across various medical conditions, but no studies have investigated its performance in people with Parkinson's disease (PD). In this study, the authors aimed to determine if the DT is valid and reliable in a sample of participants with PD recruited from a movement disorder clinic. Use of a tool such as the DT allows staff to identify and address the most distressing symptoms and refer patients on for specialist input when needed.

Keywords

Parkinson Disease; psychological distress; validation; questionnaire

Introduction

Psychological distress, including anxiety and depression, has been widely shown to be under-reported in people with Parkinson's disease (PD) and to have a negative impact on quality of life.[1] It is essential that healthcare professionals are aware of the impact of distress and can screen for this in medical settings. One widely-used brief screen is the Distress Thermometer (DT), originally developed for use with cancer patients[2] and since validated in other clinical populations. It is a visual analogue scale ranging from 0-10 with individuals required to circle the number which best represents their levels of distress in the past week, with higher scores indicating higher levels of distress. They are then asked to indicate the source of this distress under domains including practical, family and/or emotional problems, by completing the accompanying problem list (PL).

National Institute for Health and Care Excellence (NICE) guidelines for chronic health conditions state that screening tools should be used when depression is suspected, in order to inform stepped care interventions, with the DT mentioned as being a useful screening tool.[3] It can be of particular use when an individual has motor or literacy difficulties. The use of a tool such as the DT allows staff to identify and address the most distressing symptoms and refer patients on for specialist input when needed. However, the validity and reliability of the DT for identifying distress in people with PD has not been formally examined in the research literature.

This study aimed to assess the validity of the DT for detecting distress in people with PD. Test-retest reliability was also evaluated to assess the stability of the DT before and after a routine medical consultation. Lastly, this study examined responses on the PL to identify its usefulness as a potential explanation of participants' DT scores.

Materials and Methods

Participants

This study was approved by the Research and Development Department in NHS Ayrshire and Arran (reference 2019AA030) and NHS Grampian Research Ethics Committee (reference 19/NS/0112). All participants gave written informed consent after reading the study information sheet and having the opportunity to ask questions. Participants were recruited from the NHS Ayrshire and Arran Movement Disorders Clinic (MDC) in Scotland, UK. Inclusion criteria were diagnosis of idiopathic PD; registered with an MDC Consultant; able to give informed consent; able to understand and respond to the study questionnaires (carer/staff may assist with writing if necessary); aged 18 years or older. Other comorbid neurodegenerative disease (except dementia) was an exclusion criterion. The target sample size was N = 102 (see power calculation in Supplementary Information online at https://osf.io/mjt7k/). Recruitment began in October 2019 and was forced to cease in March 2020 due to the outbreak of COVID-19 and subsequent lockdown restrictions.

Measures and Procedure

The DT is an 11-point visual scale. The associated problem list used in this study was tailored for movement disorders (MD-PL; see Supplementary Tables online at https://osf.io/mjt7k/). The measure used as the comparator to examine validity was the Hospital Anxiety and Depression Scale (HADS),[4] which is a self-report measure that yields separate totals for depression and anxiety (range 0-21).

A PD nurse screened upcoming MDC appointment schedules to identify eligible patients and mailed out the study information sheet. The DT was completed by the patient in the clinic just

before their appointment (as per current routine practice). During the appointment, the healthcare professional asked eligible patients if they were willing to talk to the researcher about the study. Those who were willing met with the researcher in the clinic immediately after their appointment. After giving informed consent, participants completed the study questionnaires in the clinic (the DT again plus the HADS). Information was also collected on gender, age, employment and relationship status, year of PD diagnosis, and whether the DT score changed after the appointment compared to beforehand.

Statistical analysis

Data were analysed using SPSS version 26. Descriptive statistics were used to characterise the sample. Spearman correlations quantified the relationship between the DT and the HADS (both post-appointment). As the Bonferroni-corrected significance threshold was 0.025 for these analyses (see power calculation in Supplementary Information online at https://osf.io/mjt7k/), the 98% confidence interval (CI) is presented with these correlation estimates instead of the usual 95% CI. Spearman correlations were also used to examine test-retest stability between the pre- and post-appointment DT scores.

Descriptive statistics were reported for the number and type of problems endorsed on the MD-PL, pre- and post-appointment. Spearman correlations quantified the relationship between the DT score and number of problems identified by participants, both overall and within each of the seven problem domains. Due to the large number of correlations this entailed, Bonferroni correction was deemed to be too restrictive, and the false discovery rate (FDR) correction[5] was applied instead across these MD-PL analyses using an online calculator (https://www.sdmproject.com/utilities/?show=FDR). As the false positive rate is already

controlled by this method, the significance threshold for these results was 0.05 and the 95% CI is reported.

Results

Forty people took part; see Supplementary Information (online at https://osf.io/mjt7k/) for a flowchart of recruitment. Demographic information is presented in Table 1 and descriptive statistics for the DT and HADS in Table 2.

Is the DT a valid measure to detect distress in patients with PD?

The HADS anxiety subscale demonstrated a large, significant correlation of 0.68 with the DT, p <0.001, 98% CI 0.38 to 0.85. The HADS depression subscale also demonstrated a large, significant correlation of 0.58 with the DT, p <0.001, 98% CI 0.24 to 0.79.

Does the DT show test-retest stability in PD patients when measured before and after a medical appointment relating to their PD care?

A very large, significant pre-post correlation was observed: rho 0.98, p <0.001, 95% CI 0.96 to 0.99. The DT scores changed post-appointment for eight participants: two participants' scores decreased by one point and the other six increased by 1-2 points.

For the two participants whose DT scores had decreased, both explained that they had felt reassured talking about their diagnosis with their PD nurse. Varied reasons were given for increased scores. One participant noted that seeing all the potential problems written down increased their distress, and another reported that since completing the pre-appointment DT, they had thought more about the problems listed and identified more, leading to a higher reported level of overall distress. A third participant reported increased distress due to time pressure while

completing the study measures (needing to go to another appointment). Other reasons were linked to the emotional domain of the PL and involved issues arising during their appointment regarding limitations of treatment.

What are the most common problems endorsed on the MD-PL in this population?

Medians and quartiles for the number of problems identified per domain pre- and post-appointment are given in Supplementary Table 1 (online at https://osf.io/mjt7k/). Supplementary Table 2 (online at https://osf.io/mjt7k/) lists the types of problems endorsed.

In the physical domain, the most frequently reported problems were sleep problems and fatigue; sleep problems were endorsed by 65% both pre- and post-appointment, and fatigue was endorsed by 57.5% pre and 55% post. In the motor domain the most reported problem was walking, followed by stiffness. There were six problems not reported by any participants: odd/bizarre behaviour (cognitive domain), housing problems (practical domain), problems with relatives/friends (family domain), and none of the three problems were endorsed in the spiritual domain. Other problems not on the MD-PL but which were reported by individual participants were backache, senses, symptom change and speech impairment.

What is the correlation between pre- and post-appointment DT scores and number of problems endorsed on the PL?

A similar pattern of correlations was observed both pre- and post-appointment (Supplementary Table 3 online at https://osf.io/mjt7k/). The emotional domain demonstrated the highest correlation with the DT pre-appointment, while the cognitive domain showed the lowest correlation with the DT both pre- and post-appointment.

Discussion

The results indicate that the DT may be a valid measure to screen for distress in the PD population. The correlation sizes found in this study are at the larger end of those that have typically been found in the literature.[6 7] The present results are in line with the literature in other respects, as the HADS anxiety subscale tends to be more highly correlated with the DT than the depression subscale.[8-10] Although promising, it is important to note that the use of the DT as a screening tool should enhance, not replace, clinician judgement.[11]

The test-retest reliability results in this study indicate that the DT likely measures stable, not transient, levels of distress. This is congruent with a study in cancer patients, which found a test-retest reliability coefficient of 0.80 after 7-10 days.[12] The larger coefficient found in the present study may be due to the short duration between the two measurements.

It is important to highlight that three participants stated that their level of distress post-appointment was itself influenced by being asked to rate their distress. This may indicate that the DT can have an unintended adverse effect of increasing distress, instead of serving the intended purpose of identifying existing distress in order to provide help. This effect has been acknowledged in previous DT research.[13]

The number of problems in the physical, motor and emotional domains of the MD-PL were highly correlated with the DT score. A study in people with cancer similarly found that the DT score was most highly correlated with the physical and emotional domains.[14] In the present sample only four participants wrote in problems not represented in the MD-PL, so it is likely that the seven PL domains accurately captured the main sources of participant distress. Previous

research has indicated that the most burdensome problems in PD are in the motor domain and that concerns about these tend to increase as the disease progresses.[15]

Strengths, limitations and future directions

This is the first study to validate the use of the DT in the PD population. A strength is that it explored the PL as well as the overall DT rating of distress, as this is not typically explored in similar studies.

However, the possibility of type 1 error in this study is increased as the sample size was below the target amount determined by *a priori* power analysis. Given the lower bounds of the CIs observed in this study, it is possible that the true correlations are of a magnitude that is not reliably detectable by the current study (see sensitivity power analysis in the Supplementary Information online at https://osf.io/mjt7k/). This is a significant limitation of the current study and so the results should be interpreted with caution and require replication.

Another limitation is the largely cross-sectional nature of the study (repeated measures conducted on the same day), as the sensitivity of the DT in tracking distress over time could not be determined. Assessing distress using the DT immediately post-appointment and one week post-appointment would allow for stability over time to be assessed, in the absence of clinical influence. It could be argued that the use of the HADS as the comparator in this study was not ideal, as the HADS is itself a self-report screen. However, using more detailed diagnostic schedules to assess construct validity would not be appropriate here, as this study did not set out to identify diagnosable clinical disorders.

Conclusion

The DT shows promise and relevance as a screening tool for distress in individuals with PD; however, replication of these results is needed in a larger sample to determine reliability, generalisability and the optimal cut-off score to maximise sensitivity and specificity.

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Author Roles

1. Research project: A. Conception, B. Organization, C. Execution

2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique

3. Manuscript Preparation: A. Writing of the first draft, B. Review and Critique

BR: 1A, 1B, 1C, 2A, 2B, 3A.

SO: 1A, 1B, 2C, 3B.

BC: 1A, 1B, 2A, 2C, 3B.

Disclosures

No specific funding was received for this work. The authors declare that there are no conflicts of interest relevant to this work.

References

1. Chen JJ, Marsh L. Anxiety in Parkinson's disease: identification and management. *Therapeutic Advances in Neurological Disorders* 2014;7(1):52-59. doi: 10.1177/1756285613495723

2. Roth AJ, Kornblith AB, Batel-Copel L, et al. Rapid screening for psychologic distress in men with prostate carcinoma: A pilot study. *Cancer* 1998;82(10):1904-08. doi: 10.1002/(SICI)1097-0142(19980515)82:10<1904::AID-CNCR13>3.0.CO;2-X

3. National Institute for Health and Care Excellence. Depression in adults with a chronic physical health problem: recognition and management [CG91]. 2009 [Available from: https://www.nice.org.uk/guidance/cg91 accessed 20/04/2022.

4. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica* 1983;67(6):361-70. doi: 10.1111/j.1600-0447.1983.tb09716.x

5. Benjamini Y, Hochberg Y. Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing. *Journal of the Royal Statistical Society Series B (Methodological)* 1995;57(1):289-300. doi: 10.1111/j.2517-6161.1995.tb02031.x

6. Zwahlen D, Hagenbuch N, Carley MI, et al. Screening cancer patients' families with the distress thermometer (DT): a validation study. *Psycho - Oncology* 2008;17(10):959-66. doi: 10.1002/pon.1320

7. San Giorgi MR, Aaltonen LM, Rihkanen H, et al. Validation of the Distress Thermometer and Problem List in Patients with Recurrent Respiratory Papillomatosis. *Otolaryngology-Head and Neck Surgery* 2017;156(1):180-88. doi: 10.1177/0194599816668307

8. Gil F, Grassi L, Travado L, et al. Use of distress and depression thermometers to measure psychosocial morbidity among southern European cancer patients. *Supportive Care in Cancer* 2005;13(8):600-06. doi: 10.1007/s00520-005-0780-0

9. Geest IMM, Dorp W, Pluijm SMF, et al. The distress thermometer provides a simple screening tool for selecting distressed childhood cancer survivors. *Acta Paediatrica* 2018;107(5):871-74. doi: 10.1111/apa.14251

10. Testoni I, Sansonetto G, Ronconi L, et al. Meaning of life, representation of death, and their association with psychological distress. *Palliative & Supportive Care* 2018;16(5):511-19. doi: 10.1017/S1478951517000669

11. Mitchell AJ. Pooled Results From 38 Analyses of the Accuracy of Distress Thermometer and Other Ultra-Short Methods of Detecting Cancer-Related Mood Disorders. *Journal of Clinical Oncology* 2007;25(29):4670-81. doi: 10.1200/JCO.2006.10.0438

12. Tang L-l, Zhang Y-n, Pang Y, et al. Validation and reliability of distress thermometer in Chinese cancer patients. *Chinese Journal of Cancer Research* 2011;23(1):54-58. doi: 10.1007/s11670-011-0054-y

13. Gessler S, Low J, Daniells E, et al. Screening for distress in cancer patients: is the distress thermometer a valid measure in the UK and does it measure change over time? A prospective validation study. *Psycho - Oncology* 2008;17(6):538-47. doi: 10.1002/pon.1273

14. Tuinman MA, Gazendam-Donofrio SM, Hoekstra-Weebers JE. Screening and referral for psychosocial distress in oncologic practice: Use of the distress thermometer. *Cancer* 2008;113(4):870-78. doi: 10.1002/cncr.23622

15. Port RJ, Rumsby M, Brown G, et al. People with Parkinson's Disease: What Symptoms Do They Most Want to Improve and How Does This Change with Disease Duration? *Journal of Parkinson's Disease* 2021;11(2):715-24. doi: 10.3233/JPD-202346

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249 **Table 1:** Demographic Characteristics of the Sample (N = 40)

	N	%
Age in years		
55-64	7	17.5
65-74	14	35
75 or older	19	47.5
Gender		
Male	23	57.5
Female	17	42.5
Living arrangements		
Alone	10	25
With family or friend	30	75
Relationship status		
Single	4	10
Married or have partner	29	72.5
Widowed	6	15
Other	1	2.5
Employment status		
Employed/self-employed	3	7.5
Retired	37	92.5

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Table 2: Descriptive Statistics for Clinical Measures

	Median	Percentile	
		25th	75th
Duration of Parkinson's disease (years)	3.5	1	6
Distress Thermometer pre-appointment	3.5	1	6
Distress Thermometer post-appointment	4	1	6
HADS Anxiety	5	3	8
HADS Depression	6	4	10

HADS = Hospital Anxiety and Depression Scale

Supplementary Information for 'Preliminary Validation of the Distress Thermometer in People with Parkinson's Disease' by Bronagh Reynolds et al.

Contents

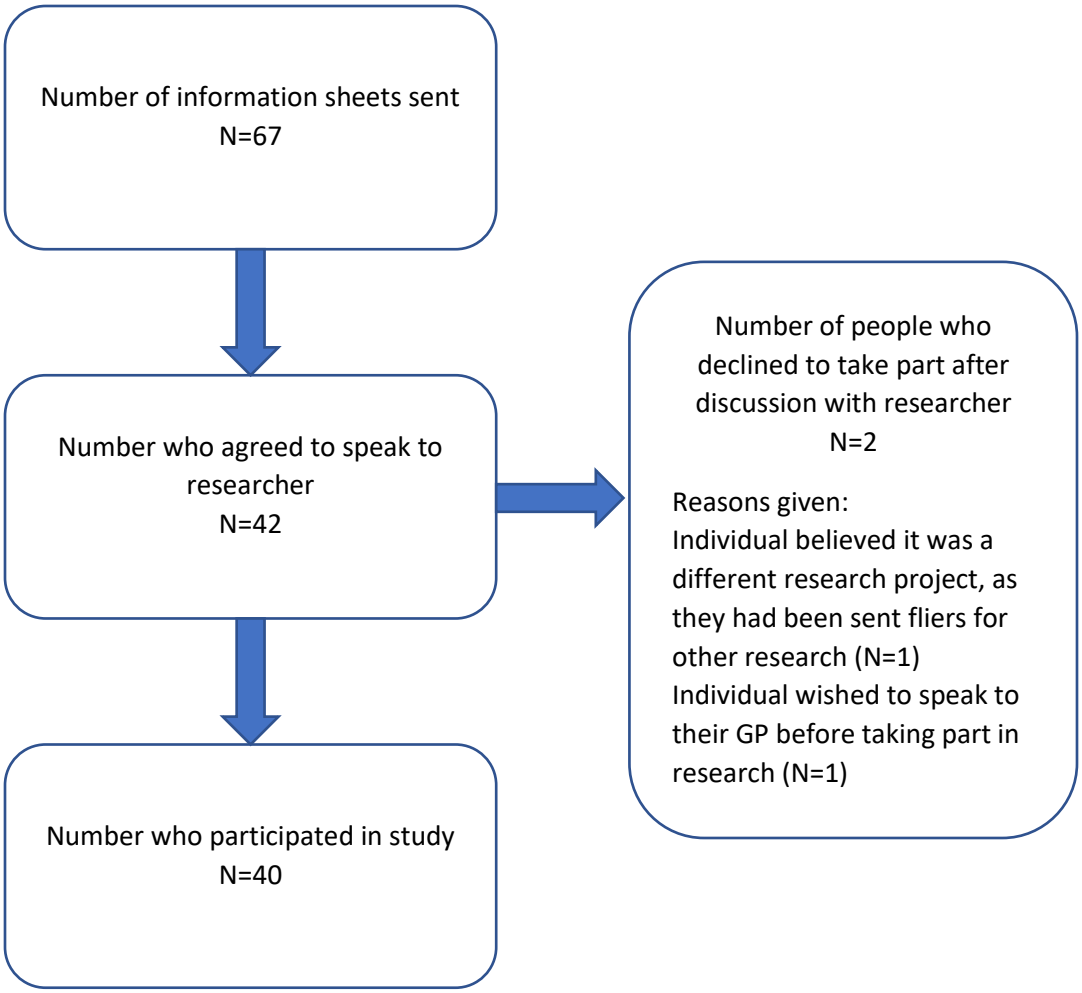
Power and sample size calculations

A priori power analysis was conducted before the study commenced, using G*power 3.1.9.2[1] to determine the required sample size. The minimum correlation level was set at 0.3 based on the estimated correlation between the DT and HADS subscales: 0.51 to 0.56 for the anxiety subscale, and 0.36 to 0.69 for the depression subscale.[2,3] As the primary research question involved two statistical tests (separately for the depression and anxiety subscales), a Bonferroni correction was applied to reduce the likelihood of type 1 error (p-value = 0.025). The parameters were: r = 0.3 (medium), p = 0.025 (two-tailed), power (1-β) = 0.80.[4] The required sample size was determined to be 102 participants.

The final sample size was N = 40, however, owing to the cessation of research activity in March 2020 as a result of the COVID-19 pandemic. A sensitivity power analysis was conducted before the data were analysed, to determine the minimum correlation size that a sample of 40 would be able to detect reliably with 80% power and two-tailed p = 0.025. This determined that a correlation of 0.46 or higher could reliably be detected by the current study. Given the lower bounds of the CIs we observed in our analyses, it is possible that the true correlations are below 0.46 and therefore not reliably detectable by the current study.

1. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using GPower 3.1: Tests for correlation and regression analyses. Behavior Research Methods 2009; 41: 1149-1160. doi:10.3758/BRM.41.4.1149
2. San Giorgi MR, Aaltonen LM, Rihkanen H, et al. Validation of the Distress Thermometer and Problem List in Patients with Recurrent Respiratory Papillomatosis. Otolaryngology-Head and Neck Surgery 2017; 156: 180-188. doi:10.1177/0194599816668307
3. Zwahlen D, Hagenbuch N, Carley MI, Recklitis CJ, Buchi S. Screening cancer patients' families with the distress thermometer (DT): a validation study. Psycho-oncology 2008; 17: 959-966. doi:10.1002/pon.1320
4. Cohen J. A Power Primer. Psychological Bulletin 1992; 112: 155-159. doi:10.1037/0033-2909.112.1.155

Supplementary Figure 1: Recruitment Flowchart



Supplementary Table 1: Descriptive Statistics for Movement Disorder Problem List Pre- and Post-Appointment

		Number of problems endorsed			**Number of problems endorsed**		
Domain	**No. problems listed**	**Pre**	**Percentile**		**Post**	**Percentile**	
		Median	**25th**	**75th**	**Median**	**25th**	**75th**
Physical	22	5	3	6.75	5	3	7
Motor	8	3	1	4	2.5	1.25	3.75
Cognitive	6	1	0	2	1	0	2
Practical	4	0	0	0	0	0	0
Family	4	0	0	0	0	0	0
Emotional	7	1	0	2	1	0	2
Spiritual	3	0	0	0	0	0	0
Total	54	9.5	6	13	9.5	6	13

Supplementary Table 2: Types of Problems Endorsed from the Movement Disorder Problem List

Problem List	**Pre**		**Post**	
	N	**%**	**N**	**%**
Physical				
Your Appearance	2	5	3	7.5
Bathing or dressing	8	20	7	17.5
Dribbling saliva	11	27.5	11	27.5
Swallowing problems	4	10	4	10
Eating/Appetite	4	10	7	17.5
Change in weight	6	15	5	12.5
Sore/dry mouth	9	22.5	9	22.5
Eating/Appetite	3	7.5	3	7.5
Nausea/Vomiting	3	7.5	3	7.5
Urinary problems	17	42.5	17	42.5
Bowel problems	12	30	14	35
Sleep problems	26	65	26	65
Nightmares	2	5	3	7.5
Acting out in sleep	3	7.5	3	7.5
Need to move legs at night	10	25	10	25
Day time sleepiness	21	52.5	16	40
Fatigue or tiredness	23	57.5	22	55
Swollen legs	8	20	9	22.5

Problem List	**Pre**		**Post**	
	N	**%**	**N**	**%**
Pain	13	32.5	13	32.5
Sweats	5	12.5	4	10
Sexual concerns	2	5	2	5
Taking medication	3	7.5	4	10
Motor				
Tremor	19	47.5	17	42.5
Fine motor control	6	15	6	15
Walking	24	60	22	55
Stiffness	18	45	19	47.5
Weakness	15	37	16	40
Freezing	9	22.5	10	25
Bed/Chair mobility	8	20	8	20
Falls	6	15	4	10
Cognitive				
Memory	13	32.5	13	32.5
Speed of thinking	11	27.5	12	30
Concentration and attention	8	20	7	17.5
Judging distance/Space	4	10	5	12.5
Odd/Bizarre behaviour	0	0	0	0
Impulsive	4	10	4	10
Practical				

Problem List	**Pre**		**Post**	
	N	**%**	**N**	**%**
Caring responsibilities	2	5	2	5
Finances, work	2	5	2	5
Housing	0	0	1	2.5
Transport/Driving	3	7.5	3	7.5
Family				
Relationship with children	1	2.5	1	2.5
Relationship with partner	1	2.5	1	2.5
Relationship with relatives/Friends	0	0	0	0
Burden (on family, friends etc)	4	10	4	10
Emotional				
Sadness or depression	10	25	11	27.5
Loneliness or isolation	5	12.5	4	10
Hopelessness	2	5	2	5
Worry, fear or anxiety	14	35	14	35
Loss of control or freedom	7	17.5	7	17.5
Anger or frustration	9	22.5	10	25
Seeing/Hearing things not there	5	12.5	5	12.5
Spiritual				
Spiritual concerns	0	0	0	0
Religious concerns	0	0	0	0
Other spiritual concerns	0	0	0	0

Supplementary Table 3: Correlations between the Distress Thermometer Score and Number of Problems Endorsed

	Pre			**Post**		
	Correlation (*rho*)	**FDR corrected p-value**	**95% confidence interval**	**Correlation (*rho*)**	**FDR corrected p-value**	**95% confidence interval**
Physical	0.62	<0.001	0.36 to 0.79	0.61	<0.001	0.34 to 0.79
Motor	0.64	<0.001	0.38 to 0.80	0.52	<0.001	0.23 to 0.73
Cognitive	0.21	0.21	-0.11 to 0.49	0.22	0.18	-0.10 to 0.50
Practical	0.21	0.21	-0.11 to 0.49	0.31	0.07	-0.01 to 0.57
Family	0.45	<0.001	0.15 to 0.68	0.35	0.04	0.03 to 0.60
Emotional	0.68	<0.001	0.44 to 0.83	0.57	<0.001	0.29 to 0.76
Total	0.76	<0.001	0.56 to 0.88	0.71	<0.001	0.48 to 0.85

FDR = False Discovery Rate

Note: No problems were endorsed in the spiritual domain and so no correlation could be calculated for this.