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An exploratory randomised trial of a nurse-led telephone support intervention for people who support people with multiple sclerosis (The MNTISS trial).

A thesis presented to the University of Dublin, Trinity College Dublin, for the Degree of Doctor of Philosophy.

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Postgraduate Diploma in Statistics.

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Appendix 1: Summary of studies on the needs and experiences of caregivers of PwMS

Author, Year, Country	Method, instruments, Participants	Findings	Use of supports/ comments
Alshubaili *et al.* (2008) Kuwait	**Design**: Survey **Sample size:** N=170 **Control:** Selected using quota sampling from WHOQol Brief data base for Kuwait to match on sex, age, occupation, marital status and level of education. **Method of data collection:** Questionnaires (26-item WHO QOL Brief, 21-item BDI, Researcher designed caregiver attitudes)	**Feelings**: Approx 2/3 expressed sadness over patient's illness; Over ½ expressed feelings of disgust, exhaustion and fear of having MS **Gender differences**: No significant sex and diagnostic differences in caregiver attitudes to MS **QoL**: Men and women had similar QoL domains; Carers of patients with RRMS tended to have higher QOL domain scores than the caregivers of patients with PMS (this trend did not reach significance). General population had significantly higher scores than carers of PwMS for all the domains (p mostly < 0.01) except for environment). Carers of PwMS had similar scores in the environment and general facet on health and QOL to carers of diabetics and psychiatric patients.	
Bogosian *et al.* (2009) UK	**Design**: Qualitative **Sample size:** N=19 **Method:** Semi-structured in-depth telephone interviews using an open-ended interview schedule.	**8 themes:** 1. Initial reactions to diagnosis (frustration and confusion provoked by the symptoms before diagnosis; difficult process to get the diagnosis; shock of the diagnosis; relief afforded by the diagnosis), 2. Loss of control, 3. Constant worry, 4. Lifestyle changes, 5. Patient having difficulty accepting new identity, 6. Debilitating symptoms/relapsing nature of ms/social isolation. 7. Relationship changes, 8. Attempts to adjust	**Response rate**: 79% (n=15)

Buchanan *et al.* (2009) USA	**Design:** National survey **Sample size:** N=530 informal caregivers **Method of data collection:** Telephone interviews using scales ranging from 0-10 for carer satisfaction with access to services and carers' perception of the quality of service (similar to scales used in the Consumer Assessment of Health Care Providers and Systems (CAHPS). Also used HRQoL using SF-8 and asked about services PwMS used, caregiver relationship to PwMS and disease characteristics of PwMSs' PwMS ability to perform Instrumental ADLs (cooking, shopping) and ADLs (personal care).	**Tasks:** Over 90% reported shopping for groceries, indoor housework, prepared meals or provide/arranged transportation for PwMS, about 40% reported that other carers also assisted the PwMS (a child was the most likely other carers) and 3 in 10 PwMS had assistance from a paid housekeeper or paid aids to assist the PwMS. **Information needs**: More than half reported needing help or information to find more time for themselves, 1/3 needed information on socialising or maintaining friendships. Others needed information on moving or lifting PwMS, managing their emotions, physical stress, finding activities they can do with the PwMS, Keeping PwMS safe at home or managing challenging behaviours or cognitive abilities. **Use of support groups**: 1 in 8 caregivers reported that they participated in support groups for informal/unpaid caregivers. Of those that attended a support group 1 in 4 informal caregivers (24.5%) reported that participating in a support group would make caregiving easier or improve the care they provide. Almost 1 in 4 (22.8%) replied that having the PwMS attend a support group would make caregivng easier or improve the care provided. More than 4 in 10 reported using the internet to learn more about caregiving, of those using the internet, more than 8 in 10 searched the internet to learn about MS or MS treatments and 3 in every 4 used the internet to learn about mobility aids or assistive devices for PwMS. About 1/3 of caregivers using the internet sought	**Services used:** Home and Community-based services for care of PwMS support group for carers, home health nurses, personal care assistants for PwMS, at home respite care, inpatient respite care. **Response rate:** not able to calculate (number of PwMS with carers unknown).

		support or advice from people with similar caregiving experiences. **Mental Health (MH) Needs**: Over 25% felt they would benefit from treatment or counselling from MH professionals; of those about 1/3 sought the services. More than 2/3 did not seek MH services for themselves either due to cost (33%) or because health insurance did not cover the cost (31%); Almost 3 in 10 thought they would benefit from MH treatment or counseling, but responded that they did not want to go to a MH professional. **Caregiver's feelings**: 9/10 reported being happy that they could help the PwMS [most of the time (39%), all of the time (52%)];; More than 8 in 10 were proud of the care they provided [most of the time (35%), all of the time (47%)]; Large majority –sense of accomplishment [most of the time (32%), all of the time (25%)]; More than half found caregiving demanding [most of the time (20%), all of the time (31%)]; Physically or emotionally draining (3 in 10 carers); 6 in 10 reported caregiving strengthened/improved relationship with PwMS [most of the time (33%), all of the time (24%)], <1 in 20 carers reported caregiving strained/threatened relationship with PwMS [most of the time (3%), all of the time (2%)].	

Buchanan *et al.* (2010) USA	**Design:** National survey **Sample size:** N=530 informal caregivers **Response rate**: Not able to calculate due to not knowing how many PwMS have carers **Method of data collection:** Telephone interviews using instruments such as 0-10 scales for carer satisfaction with access and carers perception of the quality of service (similar to scales used in the Consumer Assessment of Health Care Providers and Systems (CAHPS).	**Quality of care**: Generally satisfied with quality of routine health care and MS-focused care; < 1% reported routine care to PwMS was 'worst possible quality'; < 2% said the MS-focused care received by the PwMS was the worst possible quality; 40% of carers responded that the routine care received by the PwMS was the best possible quality and another 47% reported high level of satisfaction with quality of care; 42% said MS -focused care was the best possible quality and another 40% reported high levels of satisfaction with this care; They were less satisfied with quality of mental health care provided. **Time spent caring**: Small amounts of caregiver time was spent negotiating the health care system for the person with ms; only 13% reported spending larger amounts of time this way. They reported a larger proportion of caregiver burden or frustration caused by negotiating the health care system (mean 3.1), 18% indicated large amounts of burden or frustration caused by negotiating the health care system. **Activities:** 55% said assisting PwMS perform day to day activities took up largest amount of time, 16% reported assisting the PwMS with personal care took up largest amount of time; 11% reported addressing the psychological or emotional needs of the PwMS. **Satisfaction**: Carers generally satisfied with MS person's access to routine care (mean 7.9) and MS-focused care (mean 7.8). Only 4% reported dissatisfaction, 36%reported high levels and 40%	Support groups identified by carers as ones that improve the care provided to the PwMS: Mental health services (e.g. counselling, psychiatrist), Services for PwMS (rehabilitation, Outpatient care),

		reported total satisfaction with MS-focused care by the PwMS. They were less satisfied with access that PwMS had to home health care. 12% reported total dissatisfaction to home health care, 11% total dissatisfaction with access to rehabilitation. In contrast to MS focused care, only 30% had high levels of satisfaction with access to home health care, only 34% reported total satisfaction. Carers had similar concerns about access to rehab services by the PwMS. Only 30% had high levels of satisfaction with access to rehab services, only 33% reported total satisfaction. **Home and community services used by carers**: About 91% used mobility aids or assistive devices (for example, walkers), about 74% used home modifications e.g. Wheel chair ramps etc. About 33% group support for PwMS helped care for PwMS at home, 16% participation in caregiver support groups helped them care for PwMS. Also reports health insurance coverage.	

Finlayson & Cho (2008) USA	**Design:** Survey **Sample size:** N=32 **Method:** Telephone interviews using standard interview guide (included a series of survey-type questions about basic social and demographic information). Questions on caregivers' health and functional status, nature of help provided to the PwMS, use of and need for health for support services.	**Most common activities:** Included preparing hot meal, providing transportation, doing heavy housework (percentage and numbers also reported). Non-spousal carers were more likely to provide help to a PwMS than spouses with personal care such as managing bowel, preparing hot meal, getting dressed. **Tasks most commonly identified as challenging:** Providing transportation (n=56), helping PwMS to move around inside the house (n=54). **Most prevalent challenges:** Most prevalent challenges expressed were assisting with bowel management (43.8%, n=28), moving around inside the house (41.9%, n=54) and getting in and out of bed (40.6%, n=41). **Differences between spousal and non-spousal caregivers:** Spousal carers provided assistance with more activities compared to non-spousal carers (p=0.01). Non-spousal carers were more likely to indicate that providing assistance was challenging for providing assistance with shower or tub transfers (p=0.0236) and bladder management (p=0.023), when compared to spousal caregivers.	

Finlayson & Dahl Garcia (2008) USA	**Design:** Cross sectional study **Sample size:** N=302/343 **Response rate**: 88% **Method of data collection:** Telephone interview using an interview guide	**Activities carer provided assistance with:** Preparing hot meals (n=217, 72.3%); Providing transportation (n=209, 69.4%); Doing heavy housework (n=132, 43.7%); Doing light housework (n=1.29, 42.7%); Helping with household mobility (n=129, 43%); help with dressing (n=124, 41.2%) **Primary areas of need:** Accessing formal services; Dealing with emotional aspects of care-giving; Dealing with physical aspects of caregiving; Availability of other informal support networks; Obtaining and using assistive technology or home modifications; Managing caregiver health; Planning for the future; Understanding MS.	
Finlayson *et al.* (2009a) USA	**Design:** Pilot pre-post test **Sample size:** N=19 (unpaid caregivers of PwMS, aged 50 or over). **Method of data collection:** Mixed methods (questionnaires and focus groups (Caregiver Problem-solving and self-efficacy scales; Coping with MS Caregiving Inventory; Caregiver Preparedness Scale. **Intervention:** Group based education and problem-solving	**Pre-intervention scores** **Caregiver PS self-efficacy Scale**: Average confidence was 86% (SD =8.7, range 55-100%) **Coping with MS Caregiving Inventory** (mean scores): Avoidance (1.64, SD 0.62); Practical assistance (2.18, SD 0.61); Supportive engagement (2.90, SD 0.56); Criticism and coercion (0.96, SD 0.59); Positive reframing (2.33, SD 0.76). **Caregiver Preparedness Scale**: Mean sum of items: 14.00 SD 2.98 **Caregiver self-care self-efficacy scale**: Affirmative responses 9.16 SD:1.12; Confidence rating 92.87 SD:6.05; **Caregiver problem-solving self-efficacy scale**: Affirmative responses 3.89 sd:0.56; Confidence rating 88.28 SD:8.71	

Finlayson *et al.* (2009b) USA	**Design:** Survey **Sample size:** N=279 **Method of data collection:** Telephone interviews using closed ended survey type questions (asked about own health and activity limitations, nature of assistance provided and amount of time spent caregiving, challenges they experienced during the course of their caregiving responsibilities).	PwMS and caregivers disagree about the presence of cognitive symptoms. Gender and years the PwMS experienced symptoms were associated with type of disagreement	
McCabe *et al.* (2009) Australia	**Design:** Survey **Sample size:** N=61 carers **Method of data collection**: Postal questionnaires including subscales of the short-form profile of Mood States (POMS-SF), WHOQoL-BREF	Caregivers of PwMS required less support when compared to caregivers of people with MND and HD	

McCabe *et al.* (2008a) Australia	**Design:** qualitative **Sample size:** MS group: N=3 caregivers. **Method of data collection:** Interviews	**Services for carers reported**: Respite care (very little); Very few professional services (only 2 listed services and these were advice from GP/neurologist and osteopath treatment) **Useful services**: Carers and PwMS list the same services as helpful (most frequently listed ones were home help, cleaning, and assistance with meals). They also listed a range of services that went beyond the day-to day activities: Co-care which provides funding for taxies for outings, showering and recreation twice a week and advice-rated as an excellent service); Carers list professional societies and support groups as most helpful. **Non-useful services:** Few mentioned them but those that did focused on respite care. **Carer ideal services**: Extra assistance at home and extra respite care.	Reports on services used by caregivers Does not report finding for each group separately (included caregivers of PwMS, Parkinson's, Motor Neuron and Huntington's Disease
McCabe *et al.* (2008b) Australia	**Design:** Qualitative **Sample size:** MS group: N=3 caregivers **Method of data collection:** Interviews	Themes reported: **Impact of illness on carers' work situation** (a high % of carers reported having to cease work, reduce working hours and take time off work or sick leave due to caregiving role). **Carers' feelings about work changes** (a small number indicated positive reactions to changes in their own working lives but reactions were generally negative for changes in the work life of the PwMS. Areas of concern reported include concern about financial impact of the change, social isolation and insufficient activity for the PwMS at home.	Reports findings for caregivers of PwMS as part of overall findings. Authors claim that there was a high level of agreement regarding the themes across

		Impact of work changes on carers' social life (2 positive, having more time to go to different places and 5 negative responses, relating to social isolation, loss of friends and work colleagues. **Impact of illness on recreational activities** (very few were of the view that partner's illness improved their recreational activities, they viewed that the patient's recreational activities had deteriorated (88%, n=38).	the caregiver groups.
Rivera-Navarro *et al.* (2009) Spain	**Design:** Survey **Sample size:** N=278 **Methods**: Questionnaires (demographic questionnaire, Spanish version of the ZBI Spanish version of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36).	**Burden**: Total scores were 22.0+/-14.6 on Zarit Caregiver Burden interview; Majority of caregivers (85.6%) reported no burden using this scale. **QoL:** Most affected dimensions for caregivers were: General Health Status, Mental Health, Pain and Role-emotional functioning; Lower HRQoL scores correlated significantly with caregiver's age and gender, number of co-morbid conditions of the caregivers. **Predictors of caregiver HRQoL:** Gender (female), caregiver co-morbidities, age of carer and EDSS scores [regression coefficients ranging from -18.18 (social functioning), -5.87 (vitality) for gender; -12.82 (Role physical functioning) to -4.50 (vitality) for caregiver co-morbidities; -0.74 (Physical Functioning) to -0.26 (Role Emotional Functioning) for age of the caregiver; -5.51 (Social functioning) to - 1.11 (role-emotional functioning) for EDSS score]. Some SF-36 domain scores were also predicted by type of	

		MS (General Health and Social Functioning), age of the individual with MS (Bodily Pain) and disease-modifying treatments (General Health). Most clinical and caregiver aspects (not gender) correlated with the ZBI. **Final multiple linear regression model**: Role emotional functioning and Vitality SF-36 dimension scores and the EDSS remained significant. Remaining variables made no statistically significant contribution to the variance in the ZBI total score.	
Waldron-Perrine *et al.* (2009) USA	**Design:** Survey **Sample size:** N=64, 38 men, 26 women, spouses (75%), parents (20%) and adult children (5%). **Method of data collection:** Self-completed questionnaires (Mishel Uncertainty in Illness Scale-Community Form (MUIS-C); Awareness Questionnaire (AQ), The social Provision Scale (SPS), The Satisfaction with Life Scale (SWLS).	**Life Satisfaction**: 20.3% of caregivers reported life satisfaction more than one SD below the normative mean; 20.3% of caregivers were at least slightly dissatisfied with their life, 6.3% were dissatisfied and 1.6% were extremely dissatisfied with their lives. Alternatively 60.9% were somewhat satisfied (or better) with their lives. Income, unawareness of deficit and caregiver uncertainty in illness, made the most unique contributions to the prediction of caregiver satisfaction with life, followed by caregiver social support, illness severity and neuropsychological functioning. Stronger adverse relation between patients' level of impairment and SWLS for caregivers with low SPS (EDSS r= -0.23, NP Composite =0.47) than caregivers with high SPS (EDSS r=0.27, NP Composite = 0.07). **Gender and prediction of life satisfaction:** Income for males was higher than for females (p=0.005). Pattern of correlations for men and women separately revealed that illness severity (EDSS)	

		and duration of caregiving have stronger adverse relation to SWLS among women caregivers than men, whereas social support has a more positive relation to SWLS among women than men. However, only the difference for duration of caregiving met the rigorous Fisher's criterion, z=1.98, p=0.024. Total model accounted for 43.6% of the variance in caregiver satisfaction with life (p<0.001) (model variables: caregiver income, patient illness severity, caregiver social support, caregiver uncertainty in illness, patient unawareness of deficit, patient neuropsychological composite). ANCOVA controlling for caregiver income and PwMS neuropsychological functioning indicated a main effect of caregiver social support on life satisfaction (p=0.032) **Illness uncertainty**: This was positively related with income and education, and inversely related with social support. **Gender and social support:** A significant interaction effect was found for gender and social support (p=0.037). For caregivers with low social support, women reported lower levels of life satisfaction than men.	

Beck's Depression Inventory (BDI), Relapsing Remitting Multiple Sclerosis (RRMS), People with Multiple Sclerosis (PwMS), Quality of Life (QoL), Problem-solving (PS), Zarith Burden Interview (ZBI)

Appendix 2: Table of caregivers biographical details, length of time caring and number of hours caring

Author, Year,	Gender	Age mean years (SD, range)	Marital status	Educational level	Employment status	Length of time caregiving/number of hours/24hours providing care
Alshubaili *et al.* (2008) (N=170)	60 men; 86 women (gender of 24 caregivers not recorded)	35.7 (10.8)	Married 1-4 (71.2%)	Education: </= High school n=90 52.9%; >/= college n=80 (47.1%)	Unemployed/housewife n=54 (38%) Employed n=88 or 40.8% Men were significantly more in formal employment than the women (p<0.001)	–
Boeije & van Doorne-Huiskes (2003) (N=13)	8 men 5 women	60 (range 48-75)	–	–	3 men and 1 woman were retired; 2 changed from full-time to part-time jobs to spend more time at home	–
Bogosian *et al.* (2009) (N=15)	Male (n=10) Female (n=5)	31-40 (n=4) 41-50 (n=6) 51-60 (n=5)	–	University (n=6) College (n=7) Secondary school (n=2)	–	–

Buchanan *et al.* (2009) (N=527)	Female: 47.4	59.8 (sd. 9.9)	Married (80.2%) Divorced (8.1%) Widowed (3%) Separated (0.6%)	Graduate school (20.9%) Bachelor's degree (25.8%) Some college (27%) High school graduate or GED (19.4%) 8-11 grade (0.14%)	Full-time employment (32%) Retired (36%) Over 40% reduced the amount of time worked in previous 12 months due to caregiving responsibilities, 37% - expected that caregiving would reduce amount of time they worked in next 12 months, >3 of 4 carers reported going to work late, leaving early or taking time off in previous 12 months due to care giving responsibilities, 1 in 5 told interviewer they took a leave of absence due to caregiving demands in 12 months before interview; 1 in 5 went from full-time to part-time employment or took a less demanding job to care for the PwMS.	Average caregiving years 13.2. >20hours/week caregiving (n=49)

Cheung & Hocking (2004) (N=11)	6 men; 4 women	Range 40-60	–	–	4 gave up paid employment for the role of full-time carer	–
Courts *et al.* (2005) (N=12)	Men (n=8) Women (n=4)	Husbands 49.5 (range 31-67) Wives 55, (range 50-65)	All spouses	–	–	–
Figved *et al.* (2007) (N=76)	Male (n=45) Female (n=31)	Spouses: 45 (9.1) Children: 24.2 (7) Parents: 55.8 (17.4) Friends: 49.6 (12.1)	Mixed group	–	–	–
Finlayson & Cho (2008) USA (N=302)	Male (163, 54%) Female (139, 46%);	59.6 (SD 12.1)	–	–	Employment status: Working (part/full-time) (160, 53%), not working (142, 47%);	Hours of care provided (mean 2.8, SD. 4.1)

Finlayson *et al.* (2009a) USA (N=19)	Male (n=10) Females (n=9)	61 (9.7)	Almost 73.7% (N=14) were spouses Sibling (1, 5.3%) Child (2, 10.5%) Other relative (1, 5.3%) Friend (1, 5.3%)	High School or GED (1, 5.3%); more than high school (18, 94.7%);	Part-time (<30hours/week) (1, 5.3%). Full-time (>30hours/week) (7, 36.8%). Retired (9, 47.4%) Not working (disability) (2, 10.5%).	Less than one hou care/day (50% of carers); 1-3 hours (30%); More than 3.5hrs/day (20%).
Finlayson *et al.* (2009b) USA	Male: 54%	59.6 (13.1)	Spouses: 72%	–	53% worked outside the home	Provided care for average of 17.1 years (Sd.13.1) and for 2.75 hours/day
Forbes *et al.* *(* 2007)	Male: 154 (60%)	54 (range 50-53)	Married/partner: 227 (91%)	–	Working: 121 (50%) Retired: 83 (34%) Other 38 (16%)	–
McCabe *et al.* (2009) (N=61)	58% female	55.02 (13.26)	Married/de factto 89%	Secondary level or greater (98%)	–	–

Good *et al.* (1995) (N=65)	Male: 37 Female: 28	55 (12.6, range 25-80) for males 50 (sd. 10.1, range 34-68) for females		>96% had high school education		Male carers caring for 15.4 years (range 0 - 44, sd. 12.9) Females: 10.8 years (range 2-29, sd. 7.3)
Gregory *et al.* (1996) (N=100)	Male: n=20 (65%) Females n=11 (35%)	Median age 43 (majority between 30 and 69, range 27 to 84).	-	-	13 employed (7 full-time; 6 part-time) 8 unemployed 10 retired	1-4 hours per day (n=10) 5-10 hours per day (n=9) >10 (n=12)
Khan *et al.* (2007) (N=62)	Male: 37 (59.7%) Female: 25 (40.3%)	54.2(7.58, range 37-72).	Partner/spouse 44 (71%) Immediate family 10 (16.1%) Unknown (friend): 8 (12.9%)	–	Employed 26 (41.9%) Work hours range from 0-60, mean 21.62	–

Kleiboer *et al.* (2006) (N=57)	Women: 14%	49.3 (9.3, range 29-69)	Married: 92% Cohabiting 8%	27%: vocational education only 40% completed middle to higher levels of secondary education 33%: college degree or higher	80% employed (61% full-time, 19% part-time). Retired 11% Unemployed for other reasons (9%).	
Knight *et al.* (1997) (N=55)	Men: 33 Women:22	54.76 (10.68) for males 49.8 (9.86) for females	–	51% 3 or more years high school, 35% completed a formal qualification at high school. 35% (technical trade, nursing or teaching qualification after high school) 7% attended university.	Males: 16 full-time , 15 retired, 1 part-time, 1 seeking employment. Females: 7 employed full-time, 5 part-time, 6 working at home, 3 retired from employment.	–
Koopman *et al.* (2006) (N=353)	Male: 147 (62%)	Range 30-60 years	Spouses: 85%	High school education (220, 92%)	Employed (full or part-time) (148,66%)	

McCabe *et al.* (2008a) (N=3)	Male: n=1 Female: n=2	65.5 (4.95) range 62-69	–	–	–	–
O' Brien (1993) (N=20)	Men 11(55%) Women n=9 (45%)	Mean 52 (range 36-70)	9 (45%) caregiving wives 11 (55%) caregiving husbands	Ranged from high school to graduate degree (no figures provided)	Majority employed full-time (50%) Part-time (25%).	Average length of time providing care to spouses 8 years (range 1-25).
O'Brien *et al.* (1995) (N=61)	Males: n=34 Female: n=27	Mean: 55.2 Sd. 10.8, range 33-77.	Husbands (n=34) Wives (n=27)	2/3 some education beyond high-school	About 50% employee full or part-time	–
Pakenham (2008) (N=61)	64% male, 36% female;	52.39(13.440 range: 17-84).	Most 83% were married or in a de-facto relationship Most (79%) were a spouse, 13% an immediate family member, and 8% a close friend.	10 or more years education (90%); 31% completed a tertiary education, 18%r a trade.	Just over 53% had outside employment, 29% were retired; 3% unemployed and 9% received a carer pension. 1/3 reported that cregiving prevented them from taking on outside employment	Mean duration of caregiving was 9.17 years (SD =7.6, range 1month to 46 years. Most 91% lived with the PwMS, the majority 96% had daily contact with the PwMS.

Perrone *et al.* (2006) (N=40)	Men: 24 Women: 16	52 (11.04, range 31-84)	All spouses: years of marriage ranged from 1-60, mean 26 (SD =12.80)	_	Most worked full-time (73%) Part-time (8%) Homemakers (19%)	_
Rivera *et al.* (2003) (N=91)	Male: 30 (33%) Female: 61 (67%)	51.5 (14)	Married: 67 (73%) Single 12 (13.2%) Widowed: 11 (12.1%) Separated/divorced: 1(1.1%).	_	_	Mean time caregiving 7.6 (Sd. 5 years) Mean daily time devoted to care in house: 11.5 (Sd. 8.2)
Rivera-Navarro *et al.(* 2009) (N=278)	159 (56.8%) female	50.1 (12.6, range 19-85)	84% married or cohabiting Single 22 (7.9%)	Primary school: 122 (43.9%) Secondary school: 78 (28.1%) University: 49 (17.6%) Illiterate: 26 (9.4%) Unknown: 3 (1.1)	Most employed (144, 51.3%) Homemakers (87, 31.3%) Retired: 32 (11.5%) Unemployed: 3 (1.1%)	8.57 (7.0) (sd.5.9 (1-32) years as caregiver
Sato *et al.* (1996) (N=21)	Men (n=9) Women (n=12)	54 (range 34-78).	Most common relationship was spouse (no figures given)	Ranged from GED to doctorate degree Average: 14 years of completed education	57% caregivers employed	Cared for PwMS for an average of 16 years (range 2-34)

Waldron-Perrine *et al.* (2009) (N=64)	Male (n=38) Female (n=26)	50.7(13.5 range 20-81)	Spouses (75%) Parents (20%) Adult children of PwMS (5%)	Education: mean 15.1years, SD 2.8 range 9-20.	–	–
Winslow & O' Brien (1992) (N=61)	Male (n=34, 55.7%) Women (n=27, 44.3%)	55.2 (range 33-77)		65% (n=40) more than a high school education	49.2% (n=30) (unemployed) 50.9% (n=31) (employed either full- or part-time)	–
Wollin & Sato (2001) (N=11)	–	30 to >60	Wife/female partner (n=6) Husband/male partner (n=3) Other family member (n=1) Friend (n=1)	–	–	–
Ybema *et al.* (2002) (N=88)	Male 58 Female: 30	Mean 49 (Sd. 12, range 26-78)	All couples of which 92% were married			Duration of caregiving mean 24 years, Sd. 12, range 11months-52 years)

Appendix 3: Table of papers in progress or feasibility aspects of telephone support interventions

Author, date, country & study design	Population Intervention (I) and control (c) group	Type of intervention (single/combined; proactive/reactive; tailored/fixed; interventionist/caller initiated)	Duration, frequency, intensity & group/individual	Model used & Interventionist	Outcomes
Chang *et al.* (2004) US Presents qualitative data on an intervention sub-study on narrative reports	Caregivers of people with Dementia I: N (41) C:N (42)	Problem-solving Nurse Video with Assisted Modelling Program (NVAMP) consisted of two parts: 1. An initial 20-minute videotape that provided caregivers information on promoting self-care abilities in dressing and eating for individuals with dementia 2. Follow-up calls using the problem-solving process.	Medium: every 2 weeks for 12 weeks Length of contact: between 5 and 90mins, mean 18.3) Number in group: ranged from 1-5 (14 groups in total)	Problem-solving process no specific theory identified Two master's prepared gerontological clinical nurse specialists Training: role-play, use of open-ended questions and probes and the recording of responses.	Perceived helpfulness such as sharing thoughts and feelings, expressing feelings of being overwhelmed, discussing physical and psychosocial problems, forgetting the situation, seeking reassurance, asking for information, Several participants perceived the telephone calls to be lacking in helpfulness

Scharff (1996) US Prospective, experimental two group design with pre- and post-intervention measures	Mothers post-partum. Total SS = 28 I: N (not stated) C:N (not stated)	Mother to Mother Telephone Support Project Subjects in intervention group received a skill-building handbook. Volunteer made initial contact with the subject, introduced herself and mutually agreed upon times for calls. All other calls were initiated by either the volunteer or subject. Topics for each call could be determined by the subject, but the intervention was designed so that volunteers were provided with a list consisting of suggested questions to encourage and guide the communication between the subject and volunteer.	Low: commenced at 32 weeks gestation and call duration not clearly stated (calls weekly for a minimum of one and maximum of 3 (on average volunteers made one call per week) Length of contact: average 15 minutes /call. Number in group: N/A (one-to-one intervention)	Model of psychological empowerment (Zimmerman (1999). Trained volunteers Volunteers trained to set a helping, collaborative and supportive tone from the outset. Volunteer's role: skilled listener, as opposed to advice giver, encourage subject to realise her own knowledge and skills and use them to actively solve problems and make decisions. They were trained to convey to the subjects the knowledge and skills realised in the training sessions. Training: mostly through role play and other forms of experiential learning.	No results at time of publication. Did report that sample recruitment a challenge. Sample size small (n=28) Subject evaluations however, have consistently rated the project as excellent.

Davis (1998) US One group pre- post test design.	Caregivers of persons with Dementia I: N (17) C:N/A	Interventionist made initial home visit to each caregiver (During this visit participants received a single 2-hour intensive training session on general problem-solving and orientation to the tip sheets). Caregivers logged problem as they occurred and mailed a completed log to the interventionist, who contacted the carer each week to review the caregiving problems identified in the log.	High: weekly for 12 weeks Length of contact: 45-60 minutes. Number in group: N/A (one-to-one intervention)	Problem-solving (D'Zurilla & Nezu, 1982) Community health nurses with graduate degrees in nursing with no background/experience in dementia home care. Training: 2 stage training sequence Trained in the use of an established problem-solving model for telephone interactions with caregivers. 24 hours of didactic training in dementia using the 15 tip sheets All training sessions audio taped, used for review and critique. 10% calls recorded, reviewed and retraining given if required.	Identifies the 6 problems most frequently managed. Problem-solving moved along quickly when both carers and interventionists had copies of the tip sheets. Tip sheets alone insufficient. Interventionists had to provide additional materials in some instances. Changes over time: no significant changes over time in problem-solving styles, number of problem behaviours displayed by dementia patients or in caregivers reactions to the behaviours. Caregivers did show significant increase in use of social support, decrease in depressive symptoms; increase in life satisfaction.

Dollinger *et al.* (2006) US Intervention trial with random assignment	Rural Family Caregivers (no specific illness) I: N (42) C:N (49)	Tele-Help Line for Caregivers (TLC A multi-component intervention designed to specifically meet the needs of informal carers in a rural area. Treatment manual: organised around specified treatment objectives and or change processes associated with each of the intervention components (Knowledge component, the social-solving skills training program, social support) When participant called the interventionist listens to his/her concerns and identified and verbally delivered the TLC component most relevant to the concerns at the time.	Low-medium: 8-week (but can take longer due to caregivers' schedules or time constraints. Frequency: caregivers could call the help line whenever they wish. Length of contact: not stated Number in group: N/A (one-to-one intervention)	Perceived stress model of caregiver burden, which includes components on knowledge, skill, social support and affect Interventionists: not stated. All interventionist received formal training in the manualised treatment and research protocol and received weekly supervision.	Carer burden scores high at baseline (m: 23.2, SD=9.85), ↓ significantly showing linear trend at weeks 8 (m=17.94, SD=7.74) and 16 (m=16.75, SD=7.66). Significant effect for time and linear terms for perceived stress, depression and rumination. (not in trait-anger) Significant effect for time and linear terms for quality of life but not for mindfulness attention awareness. Satisfaction: majority satisfied.

Goelitz (2003) US One group pre-test post - test design	Caregivers of people with 11 different illnesses Number included: not stated	When accessibility is an issue: Telephone support groups for caregivers. Group sessions were to be non-structured and psycho-educational in nature Groups were designed to allow for ventilation of feelings, and to provide mutual aid and support as well as information on coping skills, self-care and relaxation techniques	Medium: weekly for 10 weeks (4 groups over a one year period) Length of sessions: set at one hour. Number in group: maximum 10 members	None stated Leaders and co-leaders (does not give any specific detail. Leaders were fixed but co-leaders could change).	Type of intervention appears to have merit for carers of patients with advanced disease. TSGM had depth and addressed themes often difficult to discuss even for in-person groups. Outlines topics being taken to the group Topics raised include death, feelings of being overwhelmed, out of control and helpless in their roles as carers.
Hauber & Jones (2002) US Comparison group approach	Families at home caring for individuals in prolonged states of reduced consciousness I: N (6) C:N (4) no follow-up except	Tele-rehabilitation (providing support for the family emotionally and reinforcement of care skills) A telemedicine system that provides simultaneous video and audio-conferencing over traditional telephone service. Objectives of the intervention: 1. Reinforce aspects of patient care the family learned during the	Low-medium: weekly visits from the CNRN via the videophone equipment for 10-12 weeks. Length of calls: between 20-45 minutes Group size: N/A one-to-one intervention.	Not stated Certified Rehabilitation Certified Nurses	Videophone group had more patients living at home and who returned to rehabilitation than the group without video conferencing. Comparison group had fewer re-hospitalisations and visits to the emergency room than the videoconferencing group. More carers in comparison group perceived that the patient required less care at the time of the interview. Needs met: group receiving tele-visits reported 58% of their needs met and 17.6% of their needs not met as opposed to the comparison group who reported 50% of their needs as met and 27.8% as not met

		inpatient stay 2. Give the family emotional support 3. Monitor the patient for changes in neurological status. Caregivers received a 30-minute hands-on training session in the use of the video conferencing equipment			
Herman *et al.* (2006) US Post-test intervention using control group and randomisation	HIV-positive patients and their caregivers. Total number of support persons (N= 76). I: (unclear) C: (unclear)	The intervention was structured to provide education, appraisal and resolution-through-referral of problems related to mood, coping and family functioning, and was similar to other telephone-based interventions. Family Intervention: Telephone Tracking (FITT) which is a telephone intervention based on the McMaster Model of family functioning. Sessions included information on HIV disease and treatment, a manual outlining the structure and goals of the telephone contacts).	Low: Total of 12 calls to be completed by the 6 month interview Weekly for the first 6 calls, two weekly for the next 4 calls and monthly for the last two calls Calls varied from 2 minute check in to nearly a full hour (11.5% were ≤ 5 minutes; 54.5 ≤ 10 minutes; 75.5% ≤ 15 minutes; 97% ≤ 30mins]). Group size: N/A one-to-one.	Telephone Tracking (FITT) model which is based on the McMaster Model of family functioning Social workers (n=3), clinical psychologists (n=4) and nurse (n=1). Training: interventionists were trained in the FITT model through didactic training. FITT model (sessions on the McMaster Model of family functioning, HIV disease and treatment, a manual outlining the structure and goals of the telephone contacts).	Participant satisfaction was high, and many reported benefits from the intervention.

Meier *et al.* (1995) US Reported on qualitative post-group telephone interviews	Caregivers of homosexual men with AIDS 11 mother caregivers I: N/A C:N/A	Telephone Support Groups (pilot project) Sessions were held via conference calls. Group leader initiated contact with members through conference calls arranged by a telephone conference organisation. Support groups designed to: provide information, reduce feelings of isolation, provide a safe environment to express feelings, provide opportunities to reflect on the meaning of losses, to consider how to confront practical and emotional aspects of death, enhance interpersonal skills to advocate for care and support, improve coping and self-care skills to manage stress.	Medium: 10 weeks (First 6 sessions were weekly; last two sessions two weeks apart). Length of calls: Eight one hour sessions Number in group: 2 groups (one with 5 participants and one with 4)	Intervention was based on an "open systems model" which emphasised helping participants learn skills to cope with personal and environmental stressors 2 leaders, both experienced group work practitioners who had previously led telephone groups for persons with HIV disease on same project (does not give any further details on the leaders).	Respondents were unanimously positive about the groups. Information received from the group was appropriate, comprehensive, and practical. Appreciated sharing ideas on care recipients eating. Many were able to finalise legal and burial arrangements which resulted in relief for some. Group provided an opportunity to explore areas of concern Commitment to the group was strong. All were comfortable with the conference call format. Access to information and support enabled them to cope with a number of stressors.

Moore (2002) US Reported on qualitative evaluation of group telephone support	Alzheimer's Disease Group telephone support	The group comprised 5 lesbian and 2 gay male caregivers.	Low: 6 sessions (frequency not stated) Number in group: 1 groups (7 participants: 5 female, 2 male)	No specific model (states that two proven human service delivery models–support groups and telephone conferencing were combined) Not stated	Concludes that traditional telephone support group service programs must understand the special concerns, issues, and needs of alternative groups in order to better evaluate and re-design current models of service deliver. The telephone support intervention offered positive reinforcement to the group of lesbian and gays caring for a partner with dementia. Highlights needs for this group that are not addressed. Findings suggest participants satisfied with the intervention.
Radziewicz *et al.* (2009) US (see comment for design)	Ageing patients with advanced cancer	The Coping and Communication Support (CCS) intervention: had choice of using telephone, email or clinic visit. Individualised to patient/caregiver preferences, accessible to older adults and the undeserved, designed to support patients and carers over the period of time when life goals and care goals are expected to shift.	Duration: has access to service for up to one year after the death to ease bereavement Frequency: 24/7 direct telephone access to primary or another covering CCSP. Length of calls: not stated Number in groups: N/A one-	Based on a model comprising two theories: health information processing style and client centred care. Coping and communication support practitioners (CCSPs) nurses with mental health training. Training: intervention manual to standardise, definitions, protocols and policies. Initial training was web-based, didactic, role-playing, reviewing scenarios. Novice	To maintain treatment fidelity researchers need to ensure that there is congruence with relevant theory, training is standardised, interventionist are competence, delivery of the intervention is monitored and documentation is also essential.

			to-one.	CCSP was partnered with experienced CCSP to observe the nurse conduct 1 or 2 face-to-face initial care conferences. Then carried out 1 or 2 contacts under the supervision of experienced CCSP.	
Sepulveda *et al.* (2008) UK One group exploratory pilot study	Caregivers of people with eating disorders I: N (14) C:N/A	Telephone coaching supplemented a DVD-based skills training.	Low: 3 months (3 sessions over the 3 months) Length of calls: 30 minutes. Number in groups: N/A one-to one.	None stated Two individuals (one professional (nurse trained in motivational interviewing), one non-professional (expert carer) did the video coaching, chosen for previous experience in dealing with people with ED)	Almost no outcome measure reached statistical significance but most of them showed improvement from baseline to post intervention General distress decreased at trend levels. Qualitative analysis: Carers found the DVD program acceptable and useful. Participants found phone coaching helped them develop skills and recognise their own shortfalls in response to the illness and with their interactions with the patient. It also helped them to better understand and appreciate the importance of commitment and readiness for change in the process of implementing changes and making progress.

Shanley *et al.* (2004) Australia	Dementia carers	Telephone support groups and were helped to organise and run 10 support groups across NSW. These included 6 groups conducted in a language other than English and one for Aboriginal carers.	Low: weekly for 5-8 weeks Length of calls: 60-90 minutes Number in groups: 4-6.	The home reach model Health and community workers (n=22)	Programme evaluated highly by the trainee group facilitators and participants. Main benefit: being able to get support and information from each other. Most felt they had been helped in some way by attending the group e.g. Felt stronger and more confident, better understand and cope with stress, better communication with family and friends.
Stewart *et al.* (2001) Canada Reports on content analysis of sessions in a pilot feasibility study using one group design	Persons with haemophilia and HIV/AIDS and family caregivers I: not clear how many C:N/A	Telephone support group intervention. The groups were created for provision of diverse types of support - informational, affirmational and emotional and were not primarily educational.	Low: 12 weeks (frequency: not stated Length of calls: not given Number in groups: 4	Process of social comparison, social exchange and social learning theory. Professional facilitator (mental health nurse) Peer facilitators of both groups were actively involved in the Society. Training: simulated situations and role play	All reported that the telephone group showed a positive impact on meeting their support needs. They believed that they had benefited from sharing information and that the support groups had decreased their feelings of isolation and loneliness.

Strawn & Hester (1998) US Within subjects one group baseline treatment design	Caregivers of people with dementia I: N 14 C: see design	Weekly telephone contacts from a caring caller (CC). Calls were structured and guided by the conversational symptom assessment (CSA), which facilitated assessment of carer needs within the context of a relatively normal conversation. Purposes of CC contacts were to (1. discuss the carers current experiences, 2. Serve as a source of social support and caring human interaction, 3. provide information) Control condition: Not outlined	High: Weekly for 12 weeks Length of calls: not stated Number in groups: N/A one-to one.	None stated Calling carer (CC) were 9 graduate students in clinical psychology Training: 8-hour training course (provides an overview of the training course) It was emphasised that CCs were to give support but not to attempt to engage in psychotherapy	Interventionists noted that the service enabled caregivers to be more independent and reach out to existing socials supports. A significant reduction in stress Baseline period: significant reduction in overall stress and stress-related responses was evident during the treatment period. Follow-up: carers highly valued tele-care and rated their CCs as caring. Most carers were sorry calls ended and one said she would be willing to pay for the service. Anecdotal evidence from CCs indicated that carers exhibited increasing self-care, reached out to existing social supports, grieved the loss of their loved ones, dealt with feelings of anger, and disclosed thoughts and feelings that they had not related to anyone else.

Smith *et al.* (2004) US	For caregivers (no specific illness identified)	Describe a TSG model Adaptation of a face-to-face telephone support group model. Assigned a group buddy and encouraged to contact in-between sessions for on-going support. During sessions problems are identified and re-framed as necessary.	High: Weekly for 12 weeks Length of calls: 1.5hrs Number in groups: not stated	None mentioned Group leader : social worker	Rarely interrupted during call-if so was due to pressing care recipient needs (Interrupted support was better than no support at all). Rarely felt that time on phone call interfered with caregiving responsibilities. Interruptions declined for later groups as they were advised to have friend or neighbour present for call duration. Overall participants enjoyed partaking in the telephone calls. Least liked: Lack of face-to-face contact; technology problems; length of meetings (some felt too long others too short).

Smith & Toseland (2006) US 2x2x2 randomised 'waitlist' control group design.	Caregivers of Frail Older Adults I: N (53) C:N (37)	The Telephone Support Group intervention (TSG) is a multi-component telephone intervention based on an adapted face-to-face support intervention that includes education on illness, emotion coping strategies, problem-solving and support 4 in-home sessions and 8 telephone follow-up calls using a leader's manual and participant book. Control: usual service offered by the senior services centers (no further detail given). Control participants were offered TSG after the initial 12-week group intervention period and completion of post-test interview.	High: Weekly for 12 weeks Length of calls: 90 minutes (15 minutes for hook-up and 75 minutes for group) Number in groups: ranged from 5-8	no specific theory identified All groups facilitated by the same licensed practicing clinical social worker Training: A practicing and licensed clinical social worker, with an MSW and PhD degree in social work provided weekly TSG consultation and supervision to the group leader.	For adult carers telephone support group intervention was more effective than usual services in reducing burden, depression, social support and pressing problems and increasing knowledge and use of community services.
Walsh & Schmidt (2003) US	Caregivers of Patients with Cancer I: N (5)	Tele-care intervention, a 4-week modification of a longer 10-week intervention for carers of patients with newly diagnosed cancer. During a home visit for	Low: weekly for 4 weeks Length of calls: not stated	Hogan's Model of Bereavement Nurse interventionist (no further details given)	Reductions in perceived depression, despair, and disorganisation despite a worsening in the patient's condition

Pilot study using one group pre-post test design		baseline data collection, the carer received a tele-care 11 workbook with instructions to review the first section before the first teleconference and a time was set for the phone calls. During the telephone sessions the interventionist used a tele-care workbook, which included weekly outlines of topics and contained information related to end-of life (EOL) and palliative care. Control: N/A	Number in groups: N/A one-to one.		
Walsh *et al.* (2004) Australia Qualitative	Caregivers of Seriously Ill Cancer	Individual Support condition (ISC), was one arm of a larger "Tele-Care" quantitative study. Goal of ISC: to enhance the caregiver's ability to cope with the stressors resulting from the patient's illness.	Medium: bi-weekly for 10 weeks. Total of 5 calls. Length of calls: up to 20 minutes (typically lasted 15-18 minutes). Number in groups: N/A one-to one.	Hogan's "Grief to Personal Growth" Nurses	Five categories were derived: 1. Bearing the burden, 2. Distressing Feelings, 3. Learning to cope, 4. Conditional well-being and 5. Feeling abandoned by others.

TLC: Tele-Help Line for Caregivers, CCS: The Coping and Communication Support intervention.

Appendix 4: R-Amstar quality evaluation instrument

R: AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews.

1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.

□ Yes□ No□ Can't answer□ Not applicable

If it satisfies 3 of the criteria 4
If it satisfies 2 of the criteria 3
If it satisfies 1 of the criteria 2
If it satisfies 0 of the criteria 1
Criteria:
(A) 'a priori' design
(B) statement of inclusion criteria
(C) PICO/PIPO research question (population, intervention, comparison, prediction, outcome)

2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

□ Yes□ No□ Can't answer□ Not applicable

If it satisfies 3 of the criteria 4
If it satisfies 2 of the criteria 3
If it satisfies 1 of the criteria 2
If it satisfies 0 of the criteria 1

□ Yes□ No□ Can't answer□ Not applicable

Criteria:
(A) There should be at least two independent data extractors as stated or implied.
(B) Statement of recognition or awareness of consensus procedure for disagreements.
(C) Disagreements among extractors resolved properly as stated or implied

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.
If it satisfies 4 or 5 of the criteria 4
If it satisfies 3 of the criteria □3
If it satisfies 2 of the criteria 2
If it satisfies 1 or 0 of the criteria 1

Criteria:
(A) At least two electronic sources should be searched.
(B) The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE).
(C) Key words and/or MESH terms must be stated **AND** where feasible the search strategy outline should be provided such that
one can trace the filtering process of the included articles.
(D) In addition to the electronic databases (PubMed, EMBASE, Medline), all searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.
(E) Journals were "hand-searched" or "manual searched" (i.e. identifying highly relevant journals and conducting a manual, page-by-page search of their entire contents looking for potentially eligible studies)

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc. (Grey literature is literature produced at all levels of government, academia, business and industry in print and electronic formats, but is not controlled by commercial publishers. Examples can be but not limited to dissertations, conference proceedings If it satisfies 3 of the criteria4 If it satisfies 2 of the criteria 3 If it satisfies 1 of the criteria 2 If it satisfies 0 of the criteria 1 Criteria: (A) The authors should state that they searched for reports regardless of their publication type. (B) The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc. (C) "Non-English papers were translated" or readers sufficiently trained in foreign language (D) No language restriction or recognition of non-English articles	□ Yes□ No□ Can't answer□ Not applicable
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided. If it satisfies 4 of the criteria 4 If it satisfies 3 of the criteria 3 If it satisfies 2 of the criteria 2 If it satisfies 1 or 0 of the criteria 1 Criteria: (A) Table/list/or figure of **included** studies, a reference list does not suffice. (B) Table/list/figure of **excluded** studies1 either in the article or in a supplemental source (i.e. online). (Excluded studies refers to those studies seriously considered on the basis of title and/or abstract, but rejected after reading the body of the text) (C) Author satisfactorily/sufficiently stated the **reason for exclusion** of the seriously considered studies. (D) Reader is able to **retrace** the included **and** the excluded studies anywhere in the article bibliography, reference, or supplemental source	□ Yes□ No□ Can't answer□ Not applicable
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported. If it satisfies 3 of the criteria 4 If it satisfies 2 of the criteria 3 If it satisfies 1 of the criteria 2 If it satisfies 0 criteria □1 Criteria: (A) In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions **AND** outcomes. (B) Provide the ranges of **relevant** characteristics in the studies analyzed (e.g. age, race, sex,	□ Yes□ No□ Can't answer□ Not applicable

relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.) (C) The information provided appears to be complete and accurate (i.e. there is a tolerable range of subjectivity here. Is the reader left wondering? If so, state the needed information and the reasoning).	
7. Was the scientific quality of the included studies assessed and documented? A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant. If it satisfies 4 of the criteria 4 If it satisfies 3 of the criteria 3 If it satisfies 2 of the criteria 2 If it satisfies 1 or 0 of the criteria 1 Criteria: (A) 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant. (B) The scientific quality of the included studies appears to be meaningful. (C) Discussion/recognition/awareness of level of evidence (D) Quality of evidence should be rated/ranked based on characterized instruments. (Characterized instrument is a created instrument that ranks the level of evidence, e.g. GRADE[Grading of Recommendations Assessment, Development and Evaluation.])	□ Yes□ No□ Can't answer□ Not applicable
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations. If it satisfies 4 of the criteria 4 If it satisfies 3 of the criteria 3 If it satisfies 2 of the criteria 2 If it satisfies 1 or 0 of the criteria 1 Criteria: (A) The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review (B) The results of the methodological rigor and scientific quality are **explicitly stated** in formulating recommendations. (C) To have conclusions integrated/drives towards a clinical consensus statement (D) This clinical consensus statement drives toward revision or confirmation of clinical practice guidelines	□ Yes□ No□ Can't answer□ Not applicable
9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?). If it satisfy 4 of the criteria □4 If it satisfy 3 of the criteria □3 If it satisfy 2 of the criteria □2 If it satisfy 1 or 0 of the following criteria 1	□ Yes□ No□ Can't answer□ Not applicable

Criteria:
(A) Statement of criteria that were used to decide that the studies analyzed were similar enough to be pooled?
(B) For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I□).
(C) Is there a recognition of heterogeneity or lack of thereof
(D) If heterogeneity exists a "random effects model" should be used and/or the rationale (i.e. clinical appropriateness) of
combining should be taken into consideration (i.e. is it sensible to combine?), or stated explicitly
(E) If homogeneity exists, author should state a rationale or a statistical test

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10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

□ Yes□ No□ Can't answer□ Not applicable

If it satisfies 3 of the criteria 4
If it satisfies 2 of the criteria 3
If it satisfies 1 of the criteria 2
If it satisfies 0 of the criteria 1
Criteria:
(A) Recognition of publication bias or file-drawer effect
(B) An assessment of publication bias should include graphical aids (e.g., funnel plot, other available tests)
(C) Statistical tests (e.g., Egger regression test).

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11. Was the conflict of interest included? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

□ Yes□ No□ Can't answer□ Not applicable

If it satisfies 3 of the criteria 4
If it satisfies 2 of the criteria 3
If it satisfies 1 of the criteria 2
If it satisfies 0 of the criteria 1

Criteria:
(A) Statement of sources of support
(B) No conflict of interest. This is subjective and may require some deduction or searching.
(C) An awareness/statement of support or conflict of interest in the **primary** inclusion studies

Appendix 5: R-AMSTAR (criteria for the evaluation of systematic reviews of mixed research designs)

R-AMSTAR items:

1. Was an 'a priori' design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristic of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of the studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest included?

Supplemental criteria for evaluation of the methodological quality of the reviews

A = Review includes *RCTs only with positive ratings for all of the criteria in the AMSTAR assessment checklist.

A - = Review includes RCTs only with positive ratings for the key items (2, 3, 6, 7 and 8) in the AMSTAR assessment checklist.

B+ = Review includes RCTs only but does not produce positive ratings for the key items (2, 3, 6, 7 and 8) in the AMSTAR assessment checklist.

B = Review includes intervention studies with a control group and a positive rating to all items in the AMSTAR assessment checklist

B- = Review includes intervention studies with a control group with

Positive ratings for the key items (2, 3, 6, 7 and 8) in the AMSTAR assessment checklist.

C+ = Review includes intervention studies with a control group but does not produce positive rating for all key items (2,3,6,7 and 8) in the AMSTAR assessment checklist.

C = Review includes before and after studies with no control groups and positive

ratings to all items in the AMSTAR assessment checklist.

C - = Review includes before and after studies with no control groups and positive ratings for key items (2, 3, 6, 7 and 8) in the AMSTAR assessment checklist.

D+ = Review includes before and after study designs with no control group and does not produce positive ratings for all key items (2, 3, 6, 7 and 8).

D = Review includes post- intervention evaluation designs and produces positive ratings to all items in the AMSTAR assessment checklist.

D- = Review includes post-intervention evaluation designs and produces positive ratings for key items (2,3,6,7 and 8) in the AMSTAR assessment checklist.

E + = Review includes post-intervention evaluation designs and does not produce positive ratings for all key items (2, 3, 6, 7 and 8) in the AMSTAR assessment checklist.

Key:

*
RCT = randomised controlled trial

Item 2 Was there duplicate study selection and data extraction?

Item 3 Was a comprehensive literature search performed?

Item 6 Were the characteristics of the included studies provided?

Item 7 Was the scientific quality of the included studies assessed and documented?

Item 8 Was the scientific quality of the included studies used appropriately in formulating conclusions?

Appendix 6: Modified Quantitative CASP Form

Author/Title/Journal

Scoring

0 – Study does not meet criteria/answer question

1 – Study partially meets criteria/gives a partially satisfactory answer to the question

2 – Study fully meets criteria/gives a fully satisfactory answer to the question

Question	Considerations/Scoring Methods	Comments	Score
1 – Does the study address a clearly focused question?	-focused in terms of population of interest -focused in terms of outcomes studied		
2 – Is the study design appropriate to address the research question?			
3 – Does the study use an appropriate sampling method?	-sampling method -time frame -sample size		
4 – Is the study sample appropriate to address the research question?	-sample characteristics clearly described -clear inclusion and exclusion criteria - appropriate controls -representativeness of sample		
5 – Is the level of non-participation tolerable?	-level of non-participation - comparison of non-participants and participants - impact of non-participation		
– Is the exposure the intervention appropriately assessed?	-definition of Telephone support provided -suitability of the indicators used -potential for bias		
7 – Are the outcomes appropriately assessed?	-validated clinical and/or survey instruments used to assess outcomes		

8 – Are known confounders accounted for?	Key confounders not identified → 0 Key confounders identified → 1 Key confounders identified and included in multivariate analysis →2		
9 – Are appropriate statistical analyses conducted?			
10– Are prevalence/risk/odds ratio measures reported with confidence intervals?	Not reported → 0 Reported without CIs → 1 Reported with CIs → 2		
11– How precise are the results?	<100 participants → 0 100-999 participants → 1 ≥1000 participants → 2		
12 - Were ethical issues appropriately considered?	-informed consent -safeguarding anonymity, confidentiality and safety -availability of support and referral options -fieldworker training		
13 Do the findings support the conclusions?			
14 - Are the findings generalisable?	Not generalisable → 0 Generalisable locally → 1 Generalisable nationally →2		
15 - Study results fit with existing evidence			

Score: /30

Appendix 7: Evaluation of telephone intervention papers using key items from the CONSORT 2010.

Study (author/date)	Adequate sequence generation/allocation Adequate/Inadequate	How was sample size determined?	Primary outcome	Secondary outcomes	Baseline characteristics similar between groups	Pilot/full trial	Achieved SS/adequacy of achieved SS
Bakas *et al.* (2009)	Sequence generation: inadequate (done by statistician, no other detail given) Allocation concealment: outcome assessors blinded but no other evidence of concealment	No (N/A pilot)	Outlines outcome measures but does not separate them into primary and secondary outcomes)	_	No significant differences reported	Pilot	I: N (26) TASK C:N (24) attention
Elliott & Berry (2009)	Unclear (no detail given)	Not stated	Yes	Does not identify any secondary outcomes	No statistically significant difference between the two groups at baseline	Full trial	N (30 in each group)

Glueckauf *et al.* (2007)	Unclear (no detail given)	Not stated	Does not separate outcome measures into primary & secondary	None identified	Significant differences for one factor. Fewer years caregiving were reported by the intervention group. Otherwise little evidence of difference between the two groups on background characteristics	states part of ongoing trial but still very small)	I: N (12) C:N (8)
Grant *et al.* (2002)	Unclear (no detail given)	Not stated	Outlines outcome measures but does not separate them into primary and secondary outcomes)	No	States that there were no significant differences amongst the groups in terms of demographic and baseline outcome variables. No table supplied.	A randomised 3-group repeated measures experimental design)	N =74 participants in total (not clear how many assigned to each group

Hartke & King (2003)	Unclear (no detail given)	Not stated	Outlines outcome measures but does not separate them into primary and secondary outcomes)	_	Treatment group had spouses more significantly impaired on the motor scale and the caregivers reported receiving significantly more help caring for spouses than the control group.	Randomised Treatment/control design (does not explicitly state it is a full trial or pilot study	I: N (43) C:N (45)
Mahoney *et al.* (2003)	Sequence generation (computer generated random assignment- no other detail given) Allocation concealment : Inadequate (envelopes)	Not stated	Outlines outcome measures but does not separate them into primary and secondary outcomes	_	No significant differences reported	RCT	I: N (49) C:N (51)
Rivera *et al.* (2008)	Simple randomisation using a table of random numbers (no detail given on who	Power analysis conducted	Yes	Yes	No baseline demographic characteristics reported	RCT	I: N (33) C:N (34)

	generated the numbers) Assigned by the second author on the paper				Only a few baseline outcome measurements reported (no difference noted by authors of this paper)		
Tremont *et al.*(2008)	Sequence generation: No detail given Allocation concealment : Not stated	Not stated	Yes	Does not identify secondary outcome measures	No significant differences in baseline characteristics reported	RCT	I: N (16) C:N (17)

SS: sample size

Appendix 8: Interview guide for NSMS

Pre-intervention delivery interview guide

Thank you (name) for participating in this interview. The interview should take no longer than 45 minutes but if you feel you have more to say on the topic we can take longer. As you have read in the information sheet the purpose of this interview is to describe the usual care you deliver to carers of PwMS so that we have a record of 'usual care'. In addition the schedule asks questions about your qualifications and number of years experience as a nurse, in order to contextualize the study findings. The information will also be used to develop the nurse led manual that will be used in the trial part of the study.

- What are the issues that carers of PwMS seek your help with?

Prompts: what things do they ask you to do for them? main problems? Examples?

- Can you describe the type of care you deliver to carers of PwMS?

Prompts: what do you do or say to help them? Examples?

- On average how often are you contacted by carers?

Prompt: weekly? monthly? the same carers?

- Are the carers usually able to make immediate contact with you or do they leave a voice message?
- If they leave a voice message, when do you usually call them back?
- Please describe how well you believe you are in a position to provide the support that carers' need?

Prompt: Enablers? Barriers?

- If you were in a position to provide 'ideal' care to carers, what would that be?

Prompt: How? What would need to happen?

- For how many years did you practices as a nurse prior to taking up a specialist post in multiple sclerosis.
- How many years experience do you have as a NSMS
- What is you highest 'Nursing Qualification'
- In addition to communication skills training as part of your nursing courses, have you completed modules or other courses which included communication skills?

Post-intervention delivery interview guide

Thank you (name) for participating in this interview. The interview should take no longer than 30-45 minutes but if you feel you have more to say on the topic we can take longer. As you have read in the information sheet the purpose of this interview is explore your experience of participating in the study and of delivering the manualised nurse-led intervention.

- Can you describe what it was like delivering the telephone support intervention?

  Prompts: extent to which you were able to provide the support required? challenges? Examples?

- Did the support persons raise issues that you were in a position to help them with?

  Prompts: what were they? Examples?

- Did the support persons raise issues that you were not in a position to help them with?

  Prompts: what were they? Examples?

- Do you think that this support service should continue to be offered to support persons?

- Are there any changes you would make to the intervention?

  Prompts: timing? Frequency of calls? Who it's offered to (e.g. newly diagnosed or for all support persons?

Appendix 9: Content Validation forms for the intervention manual

CVI form for the nurse specialist in multiple sclerosis manual.

Instructions: Please look at the nurse specialist in multiple sclerosis manual enclosed. The manual will be used by neurology nurse specialists in providing support and teaching problem-solving skills to support persons of PwMS. The manual will be used along with the support person guidebook, which support persons will receive in advance of receiving telephone calls from the nurse specialist.

The telephone call from the nurse specialist is to provide support for the support person and help him/her learn how to manage problems by identifying problems they encounter with caring, and helping them to manage these problems.

The manual contains information about the study, guidelines on telephone support services, an interview schedule to guide the nurse specialist and documentation guidelines.

The purpose of this evaluation is to determine the extent to which you believe that the manual will help the nurse specialist provide the support required by support persons and enable them to manage problems.

If you need assistance on completing this form then please contact me on Phone: 8963008, mobile (study mobile number to be inserted), Email: macorry@tcd.ie

Please rate each item in terms of its relevance to the purpose above by circling the number that best represents you view.

1 = not relevant 2 = somewhat relevant 3 = quiet relevant 4= Very relevant

For example 1 (2) 3 4

Introduction	1	2	3	4
How to use this manual	1	2	3	4
Definition of Terms	1	2	3	4
Section 1: Overview of the intervention	1	2	3	4

Section 2: Best Practice in Providing Telephone support	1	2	3	4
Models Guiding this Intervention	1	2	3	4
Egan's Model of the Skilled Helper	1	2	3	4
COPE MODEL	1	2	3	4
Section 3: Knowledge and Skill to effectively deliver the Intervention	1	2	3	4
Section 4: Interview Guide				
Call 1	1	2	3	4
Call 2 and 3	1	2	3	4
Call 4	1	2	3	4
Section 5: Documentation	1	2	3	4
Appendix 1: Frameworks Guiding Practice	1	2	3	4
Appendix 2: Strategies	1	2	3	4
Appendix 3: Resources	1	2	3	4
Appendix 4: Support person Guide	1	2	3	4

Any additional comments_____

_____

_____

_____

_____

CVI form for the support person/caregiver guidebook.

Instructions: Please look at the support person guidebook enclosed. The guidebook will be sent to support person in advance of receiving telephone calls from the nurse specialist. The telephone call from the nurse specialist is to provide support for the support person and help him/her learn how to manage supporting/caregiving by helping the support person identify problems they are encountering in their caring role, and helping them to manage problems. The guidebook contains information about the study, worksheets to help the support person prepare for the telephone calls from the nurse specialist and information on problem management. The questionnaires that the researcher will ask the support person to fill in over the telephone at various time points throughout the intervention are included at the back of the guide book.

The purpose of this evaluation is to determine the extent to which you believe that the support person guidebook informs the support person about what to expect throughout the study and prepare for the telephone calls from the nurse specialist and researcher.

If you need assistance on completing this form then please contact me on Phone: 8963008, mobile (study mobile number to be inserted), Email: macorry@tcd.ie

Please rate each item in terms of its relevance to the purpose above by circling the number that best represents you view.

1 = not relevant 2 = somewhat relevant 3 = quiet relevant 4= Very relevant

For example 1 2 3 4

(1)

Introduction	1 2 3 4
Purpose of the telephone calls	1 2 3 4
Overview of the sequence of the telephone calls	1 2 3 4
What the intervention will help you to achieve	1 2 3 4
What the intervention is not	1 2 3 4
What is a problem	1 2 3 4
Preparation for telephone calls from nurses specialists	
Worksheet 1	1 2 3 4
Worksheet 2	1 2 3 4
How to solve a problem	1 2 3 4
Outcome questionnaires	1 2 3 4

Any additional comments:_____

_____

_____

_____

_____

_____

_____

_____

CVI form (nurse specialist in multiple sclerosis training manual)

Instructions: Please look at the nurse specialist in multiple sclerosis training manual enclosed. The manual will be used to prepare the nurse specialists to use the Nurse Specialists in Multiple Sclerosis manual which you are also asked to evaluate for content relevancy for the purpose of this study.

The manual contains detailed information about the educational and psychological models underpinning this intervention and their application within the study.

The purpose of this evaluation is to determine the extent to which you believe that the training manual will help the nurse specialist deliver the intervention as outlined in the nurse specialist manual enclosed.

If you need assistance on completing this form then please contact me on Phone: 8963008, mobile (study mobile number to be inserted), Email: macorry@tcd.ie

Please rate each item in terms of its relevance to the purpose above by circling the number that best represents you view.

1 = not relevant 2 = somewhat relevant 3 = quiet relevant 4= Very relevant

For example 1 2 3 4

(1)

Introduction	1	2	3	4
The Intervention	1	2	3	4
Egan's Model of the Skilled Helper: an Overview	1	2	3	4
The Prepared Family Caregiver Model	1	2	3	4
Why both Models are used in the intervention	1	2	3	4
The approach to learning problem management	1	2	3	4
Application of the Theoretical Models to this intervention	1	2	3	4
Scenario: Application of the intervention	1	2	3	4

Appendix 10: CVI results, expert reviewer comment and changes made

CVI results for the Intervention manual

Training manual	CVI result (range)
Clarity	1
Relevance	1
Representativeness	1
Intervention component	CVI result
Clarity	1
Relevance	1
Representativeness	1
Caregiver guidebook	CVI result
Clarity	1
Relevance	1
Representativeness	0.66 – 1 Only two items receiving CVI .66 • What the intervention will help you to achieve • What the intervention is not

Comments for CVI on Support person manual

Expert reviewer (support person 1)

- "Firstly I want to say the information is excellently laid out and presented and I love the strong focus on reframing the issues faced by SPs of PwMS and the positive solution orientated approach".
- "My complements on the support booklet; it is excellently done with some important aspects covered that I was initially concerned would not be present"
- I noted a few things in the manual that jumped out at me and noted them. They don't take away from the overall quality or impact of the manual but they just struck me as odd.
- "On page 3 it reads, "does not have a magic wand and cannot solve all of the problems that you may have".... I'm concerned that some may read that as quite patronizing and insulting. While it is important to note that it's quite accurate and that the service is not a magic wand, perhaps a more tactful way of expressing that could be found.

Expert reviewer (support person 2)

- "Both the introduction and overview are clear and to the point. However, the section on page 4, "The goals of the intervention, seem to suggest that the support person is primarily a diagnostic aid, the function of which is to gauge symptoms in the person with MS they are supporting and hopefully refer them to the correct specialist.
- Suggested expanding the sections to include lifestyle support: looking at work/life balance and developing methods of accommodating those demands with newer responsibilities of caring and supporting someone with MS.
- Complemented the worksheets on problem –solving and the 'steps to managing problems but made a few word change suggestions and suggested expanding and giving more concrete examples for the steps to managing problems.
- Suggested including a 'frequently asked question or common situations action plan (CSAP)'. Thought this would probably be discussed during the call but would be an

excellent resource. Suggested that it could be emailed out to the support person after the phone call or given directly to them at a support meeting. Included a lot of detail on the CASP and also suggested that step-by-step, week-by-week action plans and checklists would be useful.

- Stated that the section on goal-setting and record-keeping was excellent but stressed the importance of not fall into the trap of 'journaling problems as it would re-inforce a negative outlook.
- Highlighted the importance of a focus on sexual issues.
- Suggested that it would be less intimidating for the questionnaires to be sent in a separate PDF.

Expert reviewer (support person 3)

- "Overall it is a fantastic idea. If it was available I would take it up"
- Felt that the wording of the first question on work sheet 2 "Why has this problem emerged" is a little aggressive in wording and would maybe lead a person to think the problem is their fault"
- Suggested word change "how do you think this problem has emerged"
- Reading what the intervention will help you achieve would lead you to believe it is more physical and medical help whereas in fact I think it is more emotional help.
- "Again I think the "intervention will help you achieve" is more emotional than physical or medical and should be laid out more or else charged so will help more physical or medical for person with MS.
- Should have other at the end of everyday tasks in worksheet 1 for cooking, laundry or other things.
- Comments for CVI on Training Manual
- Only one person commented
- Training manual - ? language for carers
- NSMS may need extra training- say a lot of understanding required

- Change name as there is a 'Jane' who is an MS nurse.

Comments for CVI on NSMS intervention

CVI reviewer comment

- I consider all the various components in the section above as very relevant to the purpose of helping the nurse specialist provide the support required by carers and enable them to manage problems

CVI reviewer comments

- This is a very thorough support manual for carers of PwMS.
- The use of Egan's model of the skilled helper and the prepared family caregiver model (COPE) within a problem management approach using Lewinian's Model of Experiential learning provides both the helper (NSMS) and the carer with a framework to manage problems.
- There is an excellent description of each model. The importance of effective use of verbal and non-verbal communication is given which I believe is fundamental to their manual in order to provide the necessary support
- It offers the helper to develop is /her self-awareness through reflective exercises and also for the carer to do so as well.
- It is a (? word) based approach to offering support which enables personal change and development. I really enjoyed reading it.

CVI reviewer comment

- Lot of work in developing nurse specialist manual. Concern that timeframe required is not feasible

CVI reviewer comment

- Great work (name of researcher) Just clarity needed on contents page

CVI reviewer comment

- Section 2 telephone support, include privacy of phone calls, ensure no distractions
- Section 3: resources: add GP contact as some issues are not MS related/other

medical symptoms

CHANGES MADE FOLLOWING EXPERT REVIEW & PILOT STUDY

Following expert review of the intervention manual a number of minor edits were made:

- The use of the name 'Jane' in the example interview was changed to 'Jasmine', as there is a nurse specialists called Jane and it may lead to some individuals assuming this example was obtained from Jane.
- On page 2- For the nurse specialists it is clarified that the term 'carer' refers to 'support person/carer'
- Throughout the support person/carer part of the manual the term 'carer' was replaced with the term 'support person/carer'
- On page 3 the type of support that the nurse specialist can offer was included.
- 'Other' included where omitted on the work sheets.
- In the work sheets the question "Why has this problem emerged?" changed to "Why do you think this problem has emerged?
- In the accompanying questionnaire where the word 'stroke' where inadvertently missed was changed to 'multiple sclerosis'
- The term 'magic wand' was removed and the sentence re-phrased "The Nurse Specialist may not be in a position to enable you to solve all of the problems you may have....."
- Importance of consistency in referring to Name of NSMS noted for study process
- The questionnaires were separated from the manual and sent in a separate PDF format

Appendix 11: The Multiple Sclerosis Impact Scale (MSIS-29)

INSTRUCTIONS:

Code XXX

This questionnaire asks about how multiple sclerosis impacts on you.

Answer every question by circling **ONE** number.

If you are unsure about how to answer a question, please give the best answer you can.

Please feel free to ask someone to assist you if you need help reading or marking the form.

alternatively, for further information and assistance, Contact:

Margarita Corry MSc. BSc.(Hons) Psych. BNS, RNT, RGN

School of Nursing & Midwifery,

24 D'Olier Street,

Dublin 2.

Phone: 8963008,

Email: macorry@tcd.ie

In the <u>past two weeks</u>, how much has your MS limited your ability to...	**Not at all**	**A little**	**Moderately**	**Quite a bit**	**Extremely**
1. Do physically demanding tasks?	1	2	3	4	5
2. Grip things tightly (eg. turn on taps)?	1	2	3	4	5
3. Carry things?	1	2	3	4	5
In the <u>past two weeks</u>, how much have you been bothered by...	Not At all	A little	Moderately	Quite A bit	Extremely
4. Problems with your balance?	1	2	3	4	5
5. Difficulties moving about indoors?	1	2	3	4	5
6. Being clumbsy?	1	2	3	4	5
7. Stiffness?	1	2	3	4	5
8. Heavy arms and/or legs?	1	2	3	4	5
9. Tremor of your arms/legs	1	2	3	4	5
10. Spasm in your limbs?	1	2	3	4	5
11. Your body not doing what you want it to do?	1	2	3	4	5
12. Having to depend on others to do things for your?	1	2	3	4	5

Please check that you have circled ONE number for EACH question

Please check that you have answered all the questions before going on to the next page

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In the <u>past two weeks</u>, how much have you been bothered by.....	Not at all	A little	Moderately	Quite a bit	Extremely
13. Limitations in your social and leisure activities at home?	1	2	3	4	5
14. Being stuck at home more than you would like to be?	1	2	3	4	5
15. Difficulties in using your hands in everyday tasks?	1	2	3	4	5
16. Having to cut down on the amount of time you spend on work or other daily activities?	1	2	3	4	5
17. Problems using transport (eg. car, bus, train, taxi etc)?	1	2	3	4	5
18. Taking longer to do things?	1	2	3	4	5
19. Difficulty doing things spontaneously (eg. going out on the spur of the moment)?	1	2	3	4	5
20. Needing to go to the toilet urgently?	1	2	3	4	5
21. Feeling unwell?	1	2	3	4	5
22. Problems sleeping?	1	2	3	4	5
23. Feeling mentally fatigued?	1	2	3	4	5
24. Worries related to your MS?	1	2	3	4	5
25. Feeling anxious or tense?	1	2	3	4	5
26. Feeling irritable, impatient or short-tempered?	1	2	3	4	5

27. Problems concentrating?	1	2	3	4	5
28. Lack of confidence?	1	2	3	4	5
29. Feeling depressed?	1	2	3	4	5

Please check that you have circled ONE number for EACH question

Did you get help to fill this form in Yes ____ No ____

If yes, who provided this help (eg. carer, researcher) _____

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Appendix 12: Multiple Sclerosis Quality of Life (MSQOL-54) questionnaire

INSTRUCTIONS:

Code XXX

This survey asks about your health and daily activities. Answer every question by circling the appropriate number (1, 2, 3, ...).

If you are unsure about how to answer a question, please give the best answer you can and write a comment or explanation in the margin.

Please feel free to ask someone to assist you if you need help reading or marking the form.

Alternatively, for further information and assistance, Contact:

Margarita Corry MSc. BSc.(Hons) Psych. BNS, RNT, RGN

School of Nursing & Midwifery,

24 D'Olier Street,

Dublin 2.

Phone: 8963008,

Email: macorry@tcd.ie

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1. In general, would you say your health is:

(circle one number)

Excellent..... 1

Very good.....2

Good.....3

Fair..... ..4

Poor..... 5

2. **Compared to one year ago**, how would you rate your health in general **now**?

(circle one number)

Much better now than one year ago..... 1

Somewhat better now than one year ago.....2

About the same 3

Somewhat worse now than one year ago 4

Much worse now than one year ago 5

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3-12. The following questions are about activities you might do during a typical day. Does **your health** limit you in these activities? If so, how much?

(Circle 1, 2, or 3 on each line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling, or stooping	1	2	3

9. Walking more than a mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing and dressing yourself	1	2	3

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13-16. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle one number on each line)

	YES	NO
13. Cut down on the amount of time you could spend on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities	1	2
16. Had difficulty performing the work or other Activities (for example, it took extra effort)	1	2

17-19. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious).

(Circle one number on each line)

	YES	NO
17. Cut down on the amount of time you could spend on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

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20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

Pain

21. How much **bodily** pain have you had during the **past 4 weeks**?

(circle one number)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(circle one number)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

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23-32. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**... (Circle one number on each line)

	All of the Time	Most Of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6

30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6
32. Did you feel rested on waking in the morning?	1	2	3	4	5	6

33. During the **<u>past 4 weeks</u>**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one number)

All of the time 1

Most of the time 2

Some of the time..... 3

A little of the time 4

None of the time 5

Health in General

34-37. How TRUE or FALSE is <u>each</u> of the following statements for you.

(Circle one number on each line)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
34. I seem to get sick a little easier than other people	1	2	3	4	5
35. I am as healthy as anybody I know	1	2	3	4	5
36. I expect my health to get worse	1	2	3	4	5
37. My health is excellent	1	2	3	4	5

Health Distress

How much of the time during the **past 4 weeks...**

(Circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
38. Were you discouraged by your health problems?	1	2	3	4	5	6
39. Were you frustrated about your health?	1	2	3	4	5	6
40. Was your health a worry in your life?	1	2	3	4	5	6
41. Did you feel weighed down by your health problems?	1	2	3	4	5	6

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Cognitive Function

How much of the time during the **past 4 weeks...**

(Circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the	Some of the Time	A Little of the Time	None of the Time
42. Have you had difficulty concentrating and	1	2	3	4	5	6
43. Did you have trouble keeping your attention	1	2	3	4	5	6
44. Have you had trouble with your memory?	1	2	3	4	5	6
45. Have others, such as family members or friends, noticed that you have trouble with your memory or problems with your concentration?	1	2	3	4	5	6

Sexual Function

46-50. The next set of questions are about your sexual function and your satisfaction with your sexual function. Please answer as accurately as possible about your function **during the last 4 weeks only.**

How much of a problem was each of the following for you **during the past 4 weeks?**

(Circle one number on each line)

MEN	**Not a problem**	**A Little of a Problem**	**Somewhat of a Problem**	**Very Much a Problem**
46. Lack of sexual interest	1	2	3	4
47. Difficulty getting or keeping an erection	1	2	3	4
48. Difficulty having orgasm	1	2	3	4
49. Ability to satisfy sexual partner	1	2	3	4

(Circle one number on each line)

WOMEN	Not a problem	A Little of a Problem	Somewhat of a Problem	Very Much a Problem
46. Lack of sexual interest	1	2	3	4
47. Inadequate lubrication	1	2	3	4
48. Difficulty having orgasm	1	2	3	4
49. Ability to satisfy sexual partner	1	2	3	4

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50. Overall, how satisfied were you with your sexual function **during the past 4 weeks**?

(circle one number)

Very satisfied 1

Somewhat satisfied..... 2

Neither satisfied nor

dissatisfied..... 3

Somewhat dissatisfied 4

Very dissatisfied..... 5

51. During the **past 4 weeks**, to what extent have problems with your bowel or bladder function interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one number)

Not at all 1

Slightly..... 2

Moderately..... 3

Quite a bit 4

Extremely..... 5

52. During the **past 4 weeks**, how much did *pain* interfere with your enjoyment of life?

(circle one number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

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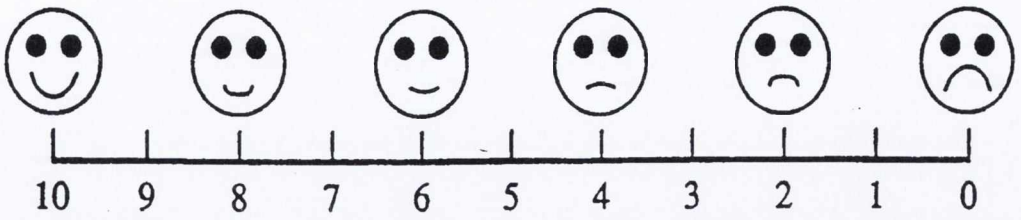
53. Overall, how would you rate your own quality-of-life?

Circle one number on the scale below:



Best Possible Quality-of-Life

Worst Possible Quality-of-Life

As bad as or worse than being dead

54.Which best describes how you feel about your life as a whole?

(circle one number)

Terrible 1

Unhappy 2

Mostly dissatisfied..... 3

Mixed - about equally

satisfied and dissatisfied 4

Mostly satisfied 5

Pleased 6

Delighted 7

Did you get help to fill this form in Yes ____ No ____

If yes, who provided this help (e.g. carer, researcher) _____

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Appendix 13: Self-Efficacy for obtaining respite and problem-solving scale questionnaire.

Code XXX

Participant Number _____ **Date**

Staff _____

Assessment # 1 2 3 4 *(Please circle)*

Revised Scale for Support person/caregiving Self-Efficacy (9/00)

"I am interested in how confident you are with managing problems that you encounter as a result of being a support person for a PwMS and how confident you are that you can ask for help. Please think about the questions I am going to read to you carefully, and be as frank and honest as you can about what you really think you can do. I will read items which cover activities and thoughts that could come up for you as a caregiver. Please think about each one and tell me how confident you are that you could do each item. Rate your degree of confidence from 0 to 100 where a 0% confidence means that you cannot do it at all, a 50% confidence means that if you gave it your best effort, chances are about 50-50 that you could perform the activity, and a 100% confidence means you are certain you can do it. You can use any score between 0 and 100 (10, 20, 30, etc.) to express your confidence. For example, a rating of 20% confidence means that it is unlikely, but not totally out of the question for you to be able to perform the activity.

0 10 20 30 40 50 60 70 80 90 100

Cannot do at all **Moderately certain can do** **Certain can do**

Please make all your ratings based on what you could do in the past week, including today, as the person you are NOW rather than on the person you used to be, or the person you would like to be. Just rate how you think you would do as you are today. Do you have any questions? We are going to do a quick practice rating to make sure everything makes sense. If you were asked to lift objects of different weights right now, how confident are you that you can:

PHYSICAL STRENGTH **CONFIDENCE (0-100)**

1. Lift a 10 pound object _____

2. Lift a 20 pound object _____

3. Lift a 50 pound object _____

4. Lift a 100 pound object _____

"Great. Let's go on. How confident are you that you can do the following activities?" (If necessary, say "If this is absolutely not applicable to your situation, let me know." Then put N/A).

Self-Efficacy for Obtaining Respite

____ 1. How confident are you that you can ask a friend/family member to stay with ___ for a day when you need to see the doctor yourself?

____ 2. How confident are you that you can ask a friend/family member to stay with ___ for a day when you have errands to be done?

____ 3. How confident are you that you can ask a friend or family member to do errands for you?

____ 4. How confident are you that you can ask a friend/family member to stay with ___ for a day when you feel the need for a break?

____ 5. How confident are you that you can ask a friend/family member to stay with ___ for a week when you need the time for yourself?

Self-Efficacy for Problem-solving

___ 6. How confident are you that you can be clear and specific in looking at supporting/caregiving problems?

____ 7. How confident are you that you can list possible solutions to a supporting / caregiving problem?

___ 8. How confident are you that you can pick the most effective method of solving a problem?

____ 9. How confident are you that you can actually carry out a plan?

Appendix 14: CVI form used to evaluate the self-efficacy in obtaining respite and problem solving

Instructions: Please look at the Self-efficacy (in problem management and obtaining respite) questionnaire. This questionnaire is being used in this study to evaluate the outcome of the intervention manual for people who support people with multiple sclerosis (family members and caregivers).

Please rate each item in terms of its 'representativeness' 'clarity' 'factors' and 'comprehensiveness' for the overall purpose of the instrument (to evaluate the outcome of the intervention manual for people who support people with MS) by circling the number that best represents your view.

Item	Representativeness	Clarity	Factors	Comprehensiveness of item
	1. Item is not Representative	1. Item is not clear	1. Focused on evaluation of the delivery of the intervention	1. Item should be deleted
	2. Item needs major revisions to be representative	2. Item needs major	2.Other, please	2. Item should be retained
	3. Item needs minor revisions to be representative	revisions to be clear	specify	
	4.Item is representative	3. Item needs minor revisions to be clear		
		4. Item is clear		

<u>Representativeness</u> refers to whether or not you believe the item represents the content of the questionnaire for evaluating the intervention for support persons of people with multiple sclerosis.

<u>Clarity</u> refers to how clear the item is to the person answering the questionnaire.

<u>Factors</u> refers to the appropriateness of the item to the evaluation of the intervention for people who support people with multiple sclerosis

<u>Comprehensiveness</u> asks you to make a judgement as to whether the item should be kept or deleted.

	Representativeness	Clarity	Focus	Comprehensiveness
Self-Efficacy in obtaining respite				
Q1:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENT:				
Q2:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENT:				
Q3:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Q4:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Q5:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Self-Efficacy for Problem-solving				
Q6:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Q7:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Q8:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENTS				
Q9:	1 2 3 4	1 2 3 4	1 2 3 4	1 2 3 4
COMMENT:				

Code 068

Appendix 15: Caregiver preparedness scale

We know that people may feel well prepared for some aspects of supporting or giving care to another person and not as well prepared for other aspects. I would like to know how well prepared you think you are to do each of the following, even if you are not doing that type of supporting or caring now.

	Not at all prepared	Not too well prepared	Somewhat well prepared	Pretty well prepared	Very well prepared
1. How well prepared do you think you are to take care of your family member's physical needs?	0	1	2	3	4
2. How well prepared do you think you are to take care of his or her emotional needs?	0	1	2	3	4
3. How well prepared do you think you are to find out about and set up services for him or her?	0	1	2	3	4
4. How well prepared do you think you are for the stress of supporting or caregiving?	0	1	2	3	4
5. How well prepared do you think you are to make supporting or caregiving activities pleasant for both you and your family member?	0	1	2	3	4
6. How well prepared do you think you are to respond to and handle emergencies that involve him/her?	0	1	2	3	4
7. How well prepared do you think you are to get help and information you need from the health care system?	0	1	2	3	4
8. Overall how well prepared do you think you are to support/care for your family member?	0	1	2	3	4

9. Is there anything specific you would like to be better prepared for?

Appendix 16: Caregiver reaction assessment questionnaire

Code 068

INSTRUCTIONS:

This questionnaire asks about how providing support/care for a person with multiple sclerosis impacts on you.

Answer every question by circling the appropriate number (1, 2, 3,.)

If you are unsure about how to answer a question, please give the best answer you can.

Please feel free to ask someone to assist you if you need help reading or marking the form.

Alternatively, for further information and assistance, Contact:

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Dublin 2.

Phone: 8963008,

Email: macorry@tcd.ie

1. I feel privileged to care for (Name of PwMS)

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	2	3	4	5

2. Others have dumped caring for (Name of PwMS) onto me.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	2	3	4	5

3 My financial resources are adequate to pay for things that are required for caregiving.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	2	3	4	5

4. My activities are centered around care for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	2	3	4	5

5. Since caring for (Name of PwMS), it seems like I'm tired all of the time.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

6. It is very difficult to get help from my family in taking care of (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

7. I resent having to take care of (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

8. I have to stop in the middle of work.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

9. I really want to care for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

10. My health has gotten worse since I've been caring for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

11. I visit family and friends less since I have been caring for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

12. I will never be able to do enough caregiving to repay (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

13. My family works together at caring for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

14. I have eliminated things from my schedule since caring for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

15. I have enough physical strength to care for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

16. Since caring for (Name of PwMS), I feel my family has abandoned me.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

17. Caring for (Name of PwMS), makes me feel good.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

18. The constant interruptions make it difficult to find time for relaxation.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

19. I am healthy enough to care for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

20. Caring for (Name of PwMS), is important to me.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

21. Caring for (Name of PwMS), has put a financial strain on the family.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

22. My family (brothers, sisters, children) left me alone to care for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

23. I enjoy caring for (Name of PwMS).

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

24. It's difficult to pay for (Name of PwMS) 's health needs and services.

Strongly disagree	Disagree	Neither agree/disagree	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

Appendix 17: The WHOQoL Brief instrument

ABOUT YOU I.D. number ☐☐☐☐

Before you begin we would like to ask you to answer a few general questions about yourself: by circling the correct answer or by filling in the space provided.

What is your **gender**? Male Female

What is your **date of birth**? _____ / _____ / _____

Day / Month / Year

What is the highest **education** you received?

None at all ☐ Primary school ☐

Secondary school ☐ Tertiary ☐

What is your **marital status**?

Single ☐ Separated ☐ Married ☐

Divorced ☐ Living as married ☐ Widowed ☐

Are you currently **ill**? Yes No

If something is wrong with your health what do you think it is?_____

On average, how much time do you spend in a 24 hour period caring for the person with Multiple Sclerosis _____ hours _____minutes

How long have you cared for the person with Multiple Sclerosis

_____ Years _____months

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.** For example, thinking about the last two weeks, a question might ask:

		Not at all	Not much	Moderately	A great deal	Completely
	Do you get the kind of support from others that you need?	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

		Not at all	Not much	Moderately	A great deal	Completely
	Do you get the kind of support from others that you need?	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks. Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

THE WHOQOL-BREF

		Very poor	Poor	Neither poor nor good	Good	Very good
1 (G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that (physical) pain prevents you from doing what you need to do?	1	2	3	4	5
4 (F11.3)	How much do you need any medical treatment	1	2	3	4	5

	to function in your daily life?					
5 (F4.1)	How much do you enjoy life?	1	2	3	4	5
6 (F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7 (F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18 (F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20 (F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21 (F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22 (F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5

23 (F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24 (F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25 (F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

.....

.....

.....

.....

THANK YOU FOR YOUR HELP

Appendix 18: Client satisfaction questionnaire

The following questions are about the service you feel you receive in relation to support provided by multiple sclerosis nurse specialists. Your responses indicate how satisfied you are with the service you receive

1. How would you rate the quality of the service you received?			
☐ Excellent	☐Good	☐ Fair	☐ Poor
2. Did you get the kind of service you wanted?			
☐ Yes, definitively	☐Yes, generally	☐No, not really	☐ No, definitively not
3. To what extent has the service met your needs?			
☐ Almost all of my needs have been met	☐ Most of my needs have been met	☐Only a few of my needs have been met	☐ None of my needs have been met
4. If a friend were in need of similar help, would you recommend our service to him or her?			
☐ Yes, definitively	☐ Yes, generally	☐ No, not really	☐No, definitively not
5. How satisfied are you with the amount of help you have received?			
☐Very satisfied	☐Mostly satisfied	☐ Indifferent or mildly dissatisfied	☐ Quite dissatisfied
6. Has the services you received helped you to deal more effectively with your problems?			
☐ Yes, they helped a great deal	☐ Yes, they helped somewhat	☐No, they really didn't help	☐ No, they seemed to make things worse
7. In an overall, general sense, how satisfied are you with the service you have received?			
☐ Very satisfied	☐ Mostly satisfied	☐ Indifferent or mildly dissatisfied	☐Quite dissatisfied
8. If you were to seek help again, would you come back to this service?			
☐ Yes, definitively	☐ Yes, generally	☐ No, not really	☐ No, definitively not

© Client Satisfaction Questionnaire (CSQ-8)

Appendix 19: PwMS pre-and post- intervention delivery interview guides

Thank you (name) for participating in this interview. The interview should take no longer than 45. The purpose of this interview is to describe the type of support/care that you receive from your support person (name of support person). As you know I have the recorder on so that I can listen to this interview again. Are you ok with that? If at any time you want me to turn off the recorder or stop the interview please let me know.

- How much care does (name of support person) provide for you?
  Prompts: frequency? type?

- Is he/she always able to provide the care you need?

  Prompts: availability? knowledge? skill? attitude?

- What would help (name of support person) to provide or continue to provide the care you need?
  Prompts: type of help? Who could provide this help?

  Probes will be used as appropriate during the interview e.g. Verbal and non-verbal cues such as silence, nodding to continue, paraphrasing

Interview schedule (PwMS post-intervention)

Thank you (name) for participating in this interview. The interview should take no longer than 45. The purpose of this interview is to describe the type of support/care that you receive from your support person (name of support person). As you know I have the recorder on so that I can listen to this interview again. Are you ok with that? If at any time you want me to turn off the recorder or stop the interview please let me know.

- How much care does (name of support person) provide for you?
  Prompts: frequency? type?

- Is he/she always able to provide the care you need?
  Prompts: availability? knowledge? skill? attitude?

- What would help (name of support person) to provide or continue to provide the care you need?
  Prompts: type of help?

- Please describe any difference you notice in the way (name of support person) provides care for you over the last few months i.e. since the start of this study?
  Prompts: what they do for you?, how they care for you?

Probes will be used as appropriate during the interview e.g. Verbal and non-verbal cues such as silence, nodding to continue, paraphrasing

Appendix 20: SP post- intervention delivery interview guide

Thank you (name) for participating in this interview. The interview should take no longer than 15 minutes. The purpose of this interview is to identify how well the intervention was administered and how satisfied you are with the telephone support intervention).

The researcher will tick the answer given by the respondent

1. Did you get two phone calls from the nurse specialist in the first month of the study?
   Yes ___ No____

2. Did you get two more phone calls (one a month) for the next two months?
   Yes ___ No___

3. Did the nurse ask questions that enabled you to verbalise your needs?
   Yes ___ No___

4. Were the phone calls helpful in meeting your needs?
   Yes ___ No___

5. Have you any recommendations for improving/further developing the intervention?
   Yes ___ No___

If yes please list them:

_____

_____

_____

Did you attend or receive any other help with managing problems you encountered as part of your role in supporting the person who has MS?

Yes ___ No___

If yes please list them (use blank sheet of paper if required):

_____

_____

6. Did you attend or receive any other training on problem management/solving during the study?

Yes ___ No___

If yes please list them (use blank sheet of paper if required):

_____

_____

_____

Additional questions:

- Did the support person guide make sense?
- Did you use the guidebook?
- Did it make sense?
- What parts of the intervention were most helpful?
- Were 4 phone calls enough?
- Did you need more? Or Less?
- Have you any suggestions for improving the intervention?
- What was it like to take part in the study?
- Was it helpful?
- Why did you take part in the study?
- As a result in taking part in the study how do you feel about making contact with the NSMS?
- Would you now make contact with her sooner than you did before participating in the intervention?
- What is your view of having a nurse deliver the intervention?
- What about another member of the Multi-disciplinary team, for example, counsellor, social worker
- What is your view of having a nurse who cares for the PwMS?
- Do you think a nurse who does not provide care to the PwMS could deliver it?
- Was participating in the study time-consuming?
- Was it in any way intrusive?
- Did you experience a significant life event during your time in the study, for example, new baby, move house (example as appropriate to the SP)

Appendix 21: Acceptability and feasibility criteria

Indicators of acceptability

ACCEPTABILITY MATRIX OF ANALYSIS (For PwMS and nominated SP)		
Criteria	**Descriptor**	**Indicators**
Appropriateness, fairness, or reasonableness of the intervention	Extent to which the participants like the components and procedures of the intervention	Calls from the nurse specialist Guidebook Call schedule Mode: telephone
Perceived **effectiveness** of the intervention	Extent to which participants felt that the intervention was helpful in enabling them to manage their problems	Helpful Not helpful
Risk: potential side-effects of the intervention	Participant's perception of disadvantages of the intervention	Reported negative effects
Convenience: suitability of the intervention	Time for participants to use the intervention Disruption caused to participant's life	Ability to receive the call Barriers to receiving the call Time commitment Lifestyle issues
Adherence: willingness to use the intervention	Extent to which participants are willing to use the intervention in future.	Feelings about calling NSMS Satisfaction with the service (CSQ)

Indicators of feasibility

Criteria	Descriptor	Indicators
Availability & quality of interventionists	Availability of interventionists to deliver the intervention as scheduled	Numbers at each site Holiday Sick Resignation
Training of interventionists	Adequacy of training to enable interventionists deliver the intervention as planned	Content of the training session Clarity Detail Adequate time allocated What might help? Difficulties or challenges in carrying out the activities with specific subgroups of the target population

Material resources	availability of all material resources for proper implementation of the intervention)	Equipment (e.g. head sets, recorders). Printed materials e.g. educational booklets, other material for distribution to participants. General supplies e.g. pens.
Context	Physical and social environment in which the intervention is implemented	Location – should be easy for nurse specialists to deliver the intervention from Access to various subgroups of target population: - where necessary amenities are in place for clients requiring assistance (e.g elevators) Characteristics (layout, furniture, ambiance) known to facilitate or hinder treatment delivery. Aspects of social environment that influence implementation of the intervention: Services offered in the department Personnel available to support the intervention Support for the intervention by other health care professionals caring for participating clients
Fidelity of intervention implementation	Extent to which interventionists adhered to the protocol for delivery of the intervention	Ease of delivery of the intervention Extent to which NSMS adhered to the principles of the intervention
Reach	Extent to which various subgroups of the population are able to participate	Access to a landline/mobile Quality of the connection Quiet location to accept the call

Appendix 22: NSMS letter of invite and information sheet

Name of Nurse Specialist
Name & Address of health care organisation
Date:

Title of the Study: An Exploratory Randomised Controlled Trial of a Manualised, Nurse-led, Telephone Intervention Support Service for People who Support of People with MS.

Dear (Name of Nurse Specialist)

My name is Margarita Corry. I am a registered nurse with specialist experience in neurological nursing and am currently undertaking a research degree at the School of Nursing and Midwifery, Trinity College Dublin. I am interested in developing and testing an intervention that will enable neurological nurse specialists to determine if a change in the way they currently offer support to people who support people with multiple sclerosis (PwMS) provides better care outcomes in terms of improved support person's self-efficacy, preparedness to support/care, reduced burden and improved quality of life. A person who supports people with MS is defined as the person identified by a person with MS as the one who provides the most emotional support or physical assistance to them and who is not a paid service provider. This person can be a partner, spouse, other family member or carer.

This study involves the testing of a newly developed manualised nurse-led telephone support intervention. Participants include neurology nurse specialists who provide care for people with multiple sclerosis, people diagnosed with multiple sclerosis and their support persons.

I have obtained ethical approval from the Faculty of Health Sciences Ethics Committee in Trinity College Dublin and (insert hospital ethics committee). I have also obtained access from the Director of Nursing in your organisation and your line manager (name of line manager).

I am writing to you to invite you to take part in this study. I invite you to read the enclosed information and consent form, where the details of your participation are outlined. I enclose a summary of the proposal for your perusal. If you are interested in partaking and collaborating in this study please sign and return the enclosed consent form Or statement of interest form and I will make contact with you.

Please do not hesitate to contact me if you require any further information regarding this study please contact me on (study dedicated number to be inserted) or email: macorry@tcd.ie. I would be pleased to meet with you if necessary to discuss this study and to answer any queries that you may have.

Yours sincerely

_____

Margarita Corry

Participant information sheet (Nurse Specialists in multiple sclerosis)

STUDY TITLE: An Exploratory Randomised Controlled Trial of a Manualised Nurse-led Telephone Intervention Support Service for People who Support People with Multiple Sclerosis.

NAME OF PRINCIPAL INVESTIGATOR: (insert name)

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to determine if a change in the way in which nurse specialists provide support to carers of people with multiple sclerosis (PwMS) results in better care outcomes for people with a diagnosis of MS and their nominated support persons.

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in this study because you are a nurse specialist who provides care to people with multiple sclerosis (PwMS) and their nominated support persons. .

The Faculty of Health Sciences Ethics Committee Trinity College Dublin and the Research Ethics Committee in (Name of Hospital) have given approval for this study to be carried out.

If, having read the information below, you would like to discuss the study further with me before deciding to participate please return the statement of interest form at the end of this sheet using the reply paid envelope provided. I will then contact you to discuss your interest in participating in the study and to answer any questions that you might have. However, if having read this information sheet you feel that you fully understand what the study is about and what you are required to do if you choose to participate, please return the signed consent form along with your contact details in the envelope provided. I will then make contact with you to further discuss your participation in the study.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty.

If you agree to participate, you will be requested to:

1. Participate in an interview about the support you current offer to people who support people with multiple sclerosis.
2. Identify, from the medical notes, PwMS who attend the neurology outpatient department in your hospital who fulfil the inclusion criteria. In order to determine if the PwMS have an adult carer you will need to ask them this when they attend for appointment. If you are satisfied that the person fulfils the inclusion criteria you will be asked to hand them an information pack. They will contact the researcher directly if they wish to partake in the study.

3. When PwMS agree to participate in the study you will be asked to complete a short biographical and medical diagnosis questionnaire from the medical notes of the person with MS (see attached).

4. You will be requested to deliver the nurse-led manualised telephone support intervention to the carers assigned to the intervention group.

   Support persons will have an equal chance of being assigned by a person independent to the study to either the intervention or control group. This will be organised by the researcher and you will be informed of which group the support person has been assigned to. A total of 100 support persons will be in the intervention group and 100 in the control group. The control group consists of the usual care that you currently offer to them. The intervention comprises four structured telephone calls to the support person over a three month period. Two calls in the first month and then one each month for the following two months of the intervention phase of the study. It is anticipated that the telephone calls will last between 30-45 minutes each but if the support person requires more support and advice it could last for a longer period of time. In order to monitor the delivery of the intervention, 10% of the telephone call

between you and the support person will be recorded or the researcher can be present during the call to observe the delivery of the intervention. You may have a copy of the recording if you wish. Prior to commencement of the intervention phase of the study you will be required to receive one-to–one training from the researcher on administration of the intervention, which should not take more than 2 hours. Additional training will be offered to you if required. Throughout the study you will be asked to keep a record of all the calls you make and receive to both the intervention and control group. This is a time commitment of between 2-3.5hours/week. As additional site are recruited this time commitment will decrease. As this is an exploratory study which is exploring the feasibility of this intervention the workload commitment will be monitored by the researcher and issues that may emerge will be addressed as required.

5. On completion of the study you will be invited to participate in an interview describing your experience of delivering the intervention. You may have access to transcripts of any or all of the interviews that you participate in.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You may not benefit directly from taking part in this study. The study is an opportunity for you to participate in a research study where an intervention manual will be developed and can be used in your practice for providing ongoing support to carers. In addition the findings will provide information as to whether a proactive approach to delivering care to carers has a more positive outcome for PwMS and their carers than the way in which it is currently delivered. Participating in this study may be viewed favourable your line managers and may be advantageous to you for future career. In addition you will have the opportunity to co-author papers with me on parts of the literature reviewed for the purpose of this study. Following data analysis you will be invited to contribute to writing the section on the context of the study and drafting of the paper, which may also be advantageous to you in your present and future career.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks associated with this study. However, if for any reason you get upset as a result of participating in the study you may contact me and I will provide details on how to access support services in the occupational health department in (Name of Hospital). If you choose to co-author papers with me you could be identified as one of the nurse specialists who participated in the study. However, your name will not be linked to any specific finding in the study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study you will not be affected in any way.

CONFIDENTIALITY

Your identity will remain confidential. Your name will not be published or linked to any of the information obtained in this study. You will be given a unique study number that is used to identify any data collected by you or from you. Data collected will be stored with this code number only. Names of participants and their study numbers are kept in a locked filing cabinet in a locked office, as well as in a database that only the researcher can access. This information is stored separately from all data collected. Your name will not appear in any report or be told to anyone who is not actively involved in the research, without prior written consent from you and your employer. However, there is no absolute guarantee that the information you provide will not be obtained by legal process or court order. Research data may be shared, as required by law, with (Name of Hospital) authorities. Furthermore, if you give information about the abuse or neglect of a minor or incapacitated adult, or make threat of harm to yourself or others, I am obliged to report this information to the relevant statutory authorities, such as the hospital management in which the person you care for attends or their general practitioner.

The data collected will be used for the purpose described in this information leaflet. Unless otherwise specified, test data gathered from this study will be maintained for 5 years.

If you choose to withdraw from the study, you are entitled to take back your approval for the use of your data. To do this, you should contact the researcher in writing. Data that has already been collected will then be destroyed (unless I am obliged under law to disclose it to the relevant statutory authorities, or unless you agree to allow use of the data already collected). If you withdraw from the study recruitment at your site will cease. In the best interest of the participants who have already consented and are assigned to the intervention group you will be asked to continue to deliver the intervention to them. However, if you choose not to, the participants will be informed that due to unexpected circumstances the study can no longer continue. As support from the nurse specialist can be obtained as part of usual care the support persons already participating in the study will be advised to make contact with you by telephone as per the usual care pathway.

COMPENSATION

This study is covered by standard institutional indemnity insurance of Trinity College Dublin. If taking part in this study harms you, there are no special compensation arrangements. If you suffer harm, then you may have grounds for legal action. Whether you receive any compensation would depend upon the outcome of your legal action.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by Margarita Corry

Will I be paid for taking part in this study? No

This study is covered by standard institutional indemnity insurance.

Will my expenses be covered for taking part in this study? Should you incur any travel expenses as a result of partaking in this study, these expenses will be reimbursed.

As a token of appreciation for you time and participation in the study a 40 Euro gift voucher will be sent to you for each person with MS/support person dyad recruited to the study. This voucher will be sent to you 6 weeks into the dyad's participation in the study.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The (Name of Hospital) Research Ethics Committee have reviewed and approved this study.

CONTACT DETAILS

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Margarita Corry who can be telephoned at (a phone dedicated to the study will be purchased and number inserted here) or e-mailed at macorry@tcd.ie.

Having read the information outlined above:

Decide if you wish to take part in the study.

Sign the enclosed statement of interest form Or Consent form and I will make contact with you to discuss the study further

Appendix 23: PwMS overall study letter of invite and information sheet

Initial letter of invite (prior to sending full information pack)

Date

Title:

An Exploratory Randomised Controlled Trial of a Nurse-led, Telephone Support Service for People who support People with MS.

Dear Sir/Madam,

My name is Margarita Corry. I am a registered nurse with experience in neurological nursing and am currently undertaking a research degree at the School of Nursing and Midwifery, Trinity College Dublin.

Many people with multiple sclerosis and the people who support them may telephone the nurse specialist in the neurology department that they attend for a variety of reasons. I am interested in finding out if there is a better way of helping the person who supports you with the day to day issues and problems that may be experienced.

I am seeking your help to find out if the way that nurse specialists support and help people with multiple sclerosis can be improved by providing a structured support service for people who provide support for them. For the purpose of this study a support person is defined as the person identified by you as the one who provides the most emotional support or physical assistance to you and who is not a paid service provider. This person can be a partner, spouse, other family member or carer.

I am asking the nurse specialist in the hospital that you attend to continue offering help to you and the person you identify as your support person as usual. The person nominated as the 'support person' will also have a chance of receiving a structured support service from the nurse specialist. The support person will have a chance of being assigned to one of two groups and the nurse specialist will give help in the usual

way to one group of support persons, and in addition to this usual support she will offer the structured support package to the other group.

If you agree to take part in this study, both you and your nominated support person will be asked to complete questionnaires. Your support person will also be asked to complete questionnaires on three occasions. If your support person is in the group that receives the structured support service they will be asked to take four calls from the nurse specialist over a three month time-frame. During these calls the nurse specialist at the hospital you attend will support the person you nominate by providing information and advice and by helping them to learn problem management skills. At the end of the study they will be asked to take part in a short telephone interview to evaluate their satisfaction with the support service.

This study has received ethical approval from the Faculty of Health Sciences research ethics committee in Trinity College Dublin and (insert hospital ethics committee). I have asked (name of nurse specialist), the multiple sclerosis nurse specialist in your hospital who is one of the nurse specialists supporting the study to give/post (researcher will delete as appropriate prior to posting) this letter of invite to you.

Additional background information on the study can be viewed at the following webpage (insert webpage link here). If you and the person who supports you are interested in hearing more about this study then please do not hesitate to contact me to discuss and I will forward a detailed information pack for you to read before you commit to participating. Please contact me on mobile: 0873683557, landline 018963008 or email: macorry@tcd.ie. Alternatively, you can complete and return the statement of interest form using the enclosed stamp addressed envelope and I will make contact with you.

Yours sincerely_____

Margarita Corry

Statement of interest form (used for site one and three)

Study Title: An Exploratory Randomised Controlled Trial of a Manualised, Nurse-led, Telephone Intervention Support Service for People who Support People with MS.

Please complete this form and return to me in the freepost envelope provided

Please tick one of the following boxes:

I am interested in hearing more about this research (if so please complete the contact details below so that the researcher can make contact with you)

Name: _____

Postal Address: _____

Phone: _____

Email: _____

Preferred time of contact: _____

Signature: _____

I do not wish to hear more about this research (It would be of great help to the researcher for the further development of this study if you would explain your reasons for this) □

Reason for not wishing to consider this study further (please use back of sheet if you need to):

_____

_____

(Should the researcher need to explore why people choose to not consider participating in this study and you are in agreement that the researcher may contact you to discuss this further then please include your contact details above. If you are not in agreement for the researcher to contact you then please do not include your contact details)

Thank you for taking the time to read this information

Letter in response to receipt of the statement of interest form

Date:

Title:

An Exploratory Randomised Controlled Trial of a Nurse-led, Telephone Support Service for People who support People with MS.

Dear (insert name),

Thank you for your interest in this study and for making contact with me for further information. I have enclosed an information sheet for you and the person who supports you. The information sheet provides full details on the study. The purpose of the study is to help the support person to learn problem management skills so that they are better able to help both you and themselves manage problems they may encounter when supporting you both now and in the future.

If after having read the information sheet you wish to discuss any of the points before you make a decision please do not hesitate to contact me on mobile: xxxxx, landline xxxx or email: xxxxx.

If you both feel that you fully understand what you will be asked to do as part of the study, please sign the enclosed consent forms and return the two of them to me in the reply paid envelope provided. I will then make contact with you to ensure you fully understand what is required when participating in the study.

If you wish, I am available to meet with both you and the person you support to explain the study and answer any questions you may have.

Once again thank you for considering taking part in this study.

I look forward to hearing from you

Yours sincerely

_____

Participant Information (PwMS)

STUDY TITLE: An Exploratory Randomised Controlled Trial of a Manualised Nurse-led Telephone Intervention Support Service for People who Support People with Multiple Sclerosis.

NAME OF PRINCIPAL INVESTIGATOR: (Name of site PI)

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to determine if a change in the way in which nurse specialists provide support to people who support people with multiple sclerosis (MS) results in better care outcomes for people with a diagnosis of MS and their named support person.

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in this study because you have a diagnosis of Multiple Sclerosis. However, to be eligible for participation you must have a diagnosis of Multiple Sclerosis which does not include a severe cognitive impairment, be over 18 years of age and be in a position to nominate an adult who supports you (over 18 years of age). For the purpose of this study this is the person who provides the most emotional or physical support for you and is not a paid service provider. The person you identify may be a spouse or partner, other family member, carer or friend. The person who supports you (from here on referred to as the 'support person') must be contactable by telephone and must not suffer from a serious mental health problem. If you cannot nominate a support person, have a diagnosed cognitive impairment or are already engaged in similar research you will not be not eligible for participation in this study.

The nurse specialist in your hospital has agreed to participate in this study and your neurologist has given permission to me to write to you and invite you to take part in this study.

I am sending you this information pack because you have returned the statement of interest form indicating that you would like to receive more information about this study.

In your pack you will find an information pack for your support person. If you are interested in the study please give the pack to your support person. I invite you to read this information and discuss participation with the person you identify as your support person.

If you and your support person would like to discuss the study further with me before deciding to participate please return the statement of interest form at the end of this sheet using the reply paid envelope provided. I will then contact you to discuss your interest in participating in the study and answer any questions that you might have. However, if having read this information sheet you feel that you fully understand what the study is about and what you are required to do if you choose to participate, please return the signed consent form along with your contact details in the envelope provided. I will then make contact with you to further discuss your participation in the study.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment in any way. Furthermore your doctor may decide to withdraw you from this study if he/she feels it is in your best interest.

If you agree to participate, you will be asked to nominate the person you identify as your support person for participation in the study. For the purpose of this study a support person is defined as a person who provides the most support or physical assistance to you, and who is not a paid service provider. Both you and your nominated support person must agree and consent to participate in the study.

During the study, the support currently offered to you and the person who supports you will continue as usual. The usual support includes attending the clinic for appointments as normal and you or the person who supports you making contact with the nurse specialist by telephone for advice and support. For people who agree to take part in the study, the person they nominate as their support person will also have a chance of receiving a more structured telephone support service initiated by the nurse specialist.

Your support person will be have an equal chance of being assigned to the structured nurse-led telephone support service (the intervention) or continue with the usual

supports available. Support persons in both groups will be asked to complete questionnaires on three occasions. If they are assigned to the nurse-led telephone support service they will also be asked to receive four phone calls from the nurse specialist who provides care for you. During these phone calls the nurse specialist will discuss with your support person various ways they go about dealing with issues and problems that they may encounter on a day to day basis when supporting you. The nurse specialist will offer information and advice if needed in order to help them provide support for you and how to look after their own wellbeing. To make sure that the intervention is delivered as required, these calls may be recorded. If the call is selected for recording, your support person will be informed before the recording begins and will be asked if they are still in agreement to have the call recorded.

In order to fully understand the findings from the study it is important to describe how multiple sclerosis has impacted on and the quality of life of the people that are being cared for. You will be asked to:

Give permission to me and the nurse specialist in your hospital to access your medical records to obtain information about you and your medical diagnosis (see attached biographical and medical diagnosis form).

Complete two questionnaires, one to determine how MS has impacted on you (the multiple sclerosis impact scale, which takes about 10 minutes to complete) the other to establish your quality of life and how this has impacted on you (the multiple sclerosis quality of life questionnaire, which takes about 15 minutes to complete). The multiple sclerosis impact consists of 29 items about how multiple sclerosis impacts on your physical, emotional, social and leisure activities. The Multiple Sclerosis Quality of Life questionnaire consists of 54 items and asks about your physical, emotional and general health, pain and sexual function. These questions can be responded to by giving them a score, for example a number between 1 and 5. You will not be asked to explain your responses or provide and further information in relations to these issues. These questionnaires can be responded to via postal questionnaire, telephone interview or face-to-face interview with the researcher. You will have the opportunity to choose how you would like to fill in these questionnaires when discussing the study with the researcher.

To determine if the change in the way in which nurse specialists offer the support is cost effective, you are also requested to give permission for your support person , in consultation with you, to complete a questionnaire on the services used by you at the beginning of the study and again at the end of the study.

To determine if the support service given to support persons makes a difference to the support received by the people they support, fifteen people with multiple sclerosis, whose support person is assigned to the nurse-led telephone support intervention, will be invited to participate in an interview exploring their experience of the care provided by their nominated support persons. All persons with MS will have an equal chance of being selected for this interview. At the end of the study the same fifteen people will again be interviewed in order to determine if there is a change in their experience of receiving support as a result of the structured support service (the intervention) given to the nominated support person. If you are selected for interview you will receive a separate information sheet and consent form for that part of the study. You may choose to be in the study even if you do not wish to participate in these interviews.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You may not benefit directly from taking part in this study but the information obtained will provide information which will add to our knowledge about how multiple sclerosis impacts on people diagnosed with multiple sclerosis, and their quality of life. It also provides an opportunity for you and your support person to be part of a study which tests whether a change in the way that nurses deliver their care makes a difference to people with MS and the people who support them. Your participation in this study will contribute greatly to the advancement of research for people who support people diagnosed with multiple sclerosis.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks associated with this study. However, if you get upset as a result of participating in the study you may contact the researcher who will provide details on how to access support services.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way.

CONFIDENTIALITY

Your identity will remain confidential. Each participant will be given a unique study number that is used to identify their data instead of their name. Data collected will be stored with this code number only. Names of participants and their study numbers are kept in a locked filing cabinet in a locked office, as well as in a database that only the researcher can access. This information is stored separately from all data collected. However, there is no absolute guarantee that the information you provide will not be obtained by legal process or court order. Research data may be shared, as required by law, with (Name of Hospital) authorities. Furthermore, if you give information about the abuse or neglect of a minor or incapacitated adult, or make threat of harm to yourself or others, I am obliged to report this information to the relevant statutory authorities.

Your name will not be published or disclosed to anyone. All information collected in this study will be treated as confidential and will be stored in a locked cabinet for which only the researcher will have access.

The data collected in this study will be used for the purpose described in this information leaflet. Unless otherwise specified, test data gathered from this study will be maintained for 5 years.

If you choose to withdraw from the study, you are entitled to take back your approval for the use of your data. To do this, you should contact the researcher in writing. Data that has already been collected will then be destroyed (unless I am obliged under law to disclose it to the relevant statutory authorities, or unless you agree to allow use of the data already collected).

COMPENSATION

Your doctors are insured by virtue of their participation in the clinical indemnity scheme. This study is covered by the standard institutional indemnity insurance of Trinity College Dublin. If taking part in this study harms you, there are no special compensation arrangements. If you suffer harm, then you may have grounds for legal

action. Whether you receive any compensation would depend upon the outcome of your legal action.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and part funded by the researcher Margarita Corry. The study is also funded by the Health Research Board through a research training fellowship award.

Will I be paid for taking part in this study? No

Will my expenses be covered for taking part in this study? You will not incur any expenses as a result of partaking in this study.

As a token of appreciation for you time and participation in the study a 20 Euro gift voucher will be sent for you along with the second set of questionnaires to your support person, which will be roughly 6 weeks into the study.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The (Name of Hospital) Research Ethics Committee have reviewed and approved this study.

CONTACT DETAILS

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Margarita Corry who can be telephoned at (insert study dedicated contact number here) or e-mailed at macorry@tcd.ie.

Having read the information outlined above:

Decide if you wish to take part in the study.

Discuss participation with your support person

Sign the enclosed statement of interest form Or Consent form and

Margarita will make contact with you to discuss the study further

Appendix 24: PwMS letter of invite and interview information sheet

Margarita Corry
School of Nursing &
Midwifery,
24 D'Olier Street,
Dublin 2.
Date:

Title of the Study: An Exploratory Randomised Controlled Trial of a Manualised, Nurse-led, Telephone Intervention Support Service for People who Support People with MS.

Dear Sir/Madam,

My name is Margarita Corry. I am a registered nurse with specialist experience in neurological nursing and am currently undertaking a research degree at the School of Nursing and Midwifery, Trinity College Dublin. Thank you for agreeing to participate in this study and for nominating a support person. . You may recall that in the information sheet I gave to you at the start of this study it stated that fifteen people with multiple sclerosis whose nominated support person is assigned to the intervention part of the study would be invited to participate in an interview about the type of care they receive from their carer.

Each person with MS whose support person was assigned to the intervention had an equal chance of being invited. I am inviting you to take part in this part of the study because your name corresponded to the number that was selected from the list. Please read the information sheet about the interview part of the study and if you are interested in taking part please return the statement of interest form at the end of the information sheet which states that you would like to discuss this part of the study in more detail with me before making a decision. Alternatively, you can contact me via (study dedicated number to be inserted) or email: macorry@tcd.ie.

I will then contact you to discuss your interest in participating in this part of the study and answer any question that you may have. Please note that although you have agreed to nominate a support person and complete the questionnaires for this study you are under no obligation to participate in the interviews.

If you choose to take part in the interviews I will meet with you in a place of convenience for you to talk about the type of support or care you receive from your nominated support person. . At the end of the study I will invite you to meet with me again to discuss the type of support you receive and whether it has changed as a result of your support person participating in this study.

Yours sincerely

_____

Margarita Corry

Participant information sheet (PwMS INTERVIEWS)

STUDY TITLE: An Exploratory Randomised Controlled Trial of a Manualised Nurse-led Telephone Intervention Support Service for People who Support People with Multiple Sclerosis.

NAME OF PRINCIPAL INVESTIGATOR: (insert name of hospital PI)

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to determine if a change in the way in which nurse specialists provide support to people who support people with multiple sclerosis (PwMS) results in better care outcomes for people with a diagnosis of MS and the person who supports them.

WHY HAVE I BEEN CHOSEN?

You may recall that the information sheet given at the beginning of the study stated that fifteen people with multiple sclerosis would be selected and invited to participate in an interview on their experience of receiving support from their nominated support person , at the start of the study and again at the end of the study. The purpose of these interviews is to determine if the support intervention received by the support person makes a difference to experience of support provided by them to the people they support. All people with MS whose support person received the telephone support intervention had an equal chance of being selected for these interviews. You have been selected for this set of interviews.

WHAT WILL HAPPEN IF I VOLUNTEER?

If you agree to volunteer you will be asked to take part in an interview about your experience of being supported/cared for by your nominated support person/ carer. This interview will take place in a location of convenience for you. I can travel to your home or arrange an interview room in a place that is convenient for you.

I would like to meet with you for about 45 minutes to talk with you about how your support person provides helps or support you. After this, I will invite you to meet me again, in three to four months time for a further 45 minutes to again discuss how your support person supports you and to determine if the support you receive has changed as a result of the support offered to your support person. With your permission I would like to record our interviews so I can listen to them after we are finished talking. After this I will listen to the interviews of all of the people with multiple sclerosis who participate in this part of the study in order to describe how nominated support persons/carers provide support/care for people with multiple sclerosis, from the perspective of the person with multiple sclerosis and to see if there is a difference in the care they experience as a result of the structured support service offered during this study. . You may have access to the written form of your interviews if you wish.

The findings from all of the interviews will be combined and used as part of the overall study findings, which will be written up as a thesis and submitted for PhD purposes. The findings from the interviews will also be submitted for publication in academic journals.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You may not benefit directly from taking part in this study but doing so provides an opportunity for you to tell me about how you experience care from your carer and its impact on your life. The results may help to find ways of improving the experiences and care provided by carers of people with multiple sclerosis. They will also contribute to the evaluation of the support service offered to carers, which will enable nurse specialists determine how they practice in order to provide the best care for people with multiple sclerosis and their carers'.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks associated with this study. Sometimes however talking about your experiences of being cared for may be upsetting. Should you find this upsetting, we can stop the interview any time or we can continue with the interview and/or if you wish we can reschedule the interview for another time. Your wishes will be respected. If I feel that the interview has been too upsetting or distressing, I will, with your

permission, contact your carer to let him/her know what has happened. You may have access to transcripts of any or all of the interviews that you participate in.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way. Your participation in this study is voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment in any way. Furthermore your doctor may decide to withdraw you from this study if he/she feels it is in your best interest.

CONFIDENTIALITY

Your identity will remain confidential. Each participant will be given a unique study number that is used to identify their data instead of their name. Data collected will be stored with this code number only. Names of participants and their study numbers are kept in a locked filing cabinet in a locked office, as well as in a database that only the researcher can access. This information is stored separately from all data collected. Your name will not appear in any published material or the dissertation which will be submitted for PhD purposes or be told to anyone else involved with this study. However, there is no absolute guarantee that the information you provide will not be obtained by legal process or court order. Research data may be shared, as required by law, with (Name of Hospital) authorities. Furthermore, if you give information about the abuse or neglect of a minor or incapacitated adult, or make threat of harm to yourself or others, I am obliged to report this information to the relevant statutory authorities. As a registered nurse, I am obliged under the Code of Professional Practice, An Bord Altranais to report anything that you reveal that indicates that the care you are in receipt of is due to poor professional practice to the authorities where professional care is provided for you.

The data collected in this study will be used for the purpose described in this information leaflet. Unless otherwise specified, test data gathered from this study will be maintained for 5 years.

If you choose to withdraw from the study, you are entitled to take back your approval for the use of your data. To do this, you should contact the researcher in writing. Data

that has already been collected will then be destroyed (unless I am obliged under law to disclose it to the relevant statutory authorities, or unless you agree to allow use of the data already.

COMPENSATION

Your doctors are insured by virtue of their participation in the clinical indemnity scheme. This study is covered by the standard institutional indemnity insurance of Trinity College Dublin. If taking part in this study harms you, there are no special compensation arrangements. If you suffer harm, then you may have grounds for legal action. Whether you receive any compensation would depend upon the outcome of your legal action.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by Margarita Corry
Will I be paid for taking part in this study? No – There is no additional gratuity for partaking in this part of the study.
Will my expenses be covered for taking part in this study? Should you incur travel costs for partaking in this part of the study they will be re-imbursed.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The (Name of Hospital) Research Ethics Committee have reviewed and approved this study.

CONTACT DETAILS

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Margarita Corry who can be telephoned at (insert study dedicated contact number here) or e-mailed at macorry@tcd.ie.
Having read the information outlined above:

- Decide if you wish to take part in the study.
- Sign the enclosed statement of interest form Or Consent form and Margarita will make contact with you to discuss the study further

Appendix 25: Checklist prior to interview

1. Confirm that the interview is going ahead as scheduled
2. Instigate lone researcher guidelines
3. Bring the following:
    - schedule,
    - Information sheet
    - 2 copies of consent form
    - Dictaphone (spare dictaphone if possible)
    - AA route directions
    - Mobile phone
    - Pen for signatures
    - Note pad for note taking immediately after the interview or if the dictaphone doesn't work.
    - Full name, address and telephone contact for destination

Appendix 26: SP letter of invite and information sheet

Margarita Corry
School of Nursing & Midwifery,
24 D'Olier Street,
Dublin 2.

Date:

Title of the Study: An Exploratory Randomised Controlled Trial of a Manualised, Nurse-led, Telephone Intervention Support Service for People who Support People with MS.

Dear Sir/Madam or (Name of Nominated Support person if known to the researcher from the statement of interest form)

My name is Margarita Corry. I am a registered nurse with specialist experience in neurological nursing and am currently undertaking a research degree at the School of Nursing and Midwifery, Trinity College Dublin. I am interested in developing and testing an intervention that will enable neurological nurse specialists to determine if a change in the way they currently offer support to people who support people with MS results improvement in the support person's self-efficacy, preparedness to support/care, reduction in burden and improvement in quality of life. A person who supports people with MS is defined as the person identified by a person with MS as the one who provides the most emotional support or physical assistance to them and who is not a paid service provider. This person can be a partner, spouse, other family member or carer.

I am contacting you because the person you provide support for (is interested in taking part in this study/ has asked for further information about the study ***delete as appropriate***) and has nominated you as their support person. . I invite you to read the information sheet attached where the details of the study and what I will be asking you to do should you agree to participate in the study are outlined.

Please do not hesitate to contact me if you require any further information regarding this study before making a decision. Please contact me on (study dedicated number to be inserted) or email: macorry@tcd.ie. Alternatively, you can complete and return the statement of interest form, which is attached to the end of the information sheet, in the freepost envelope addressed to me, which is included in your information pack and I will make contact with you.

Yours sincerely,

_____

Margarita Corry

Participant information and consent form (Support persons)

STUDY TITLE: An Exploratory Randomised Controlled Trial of a Manualised Nurse-led Telephone Intervention Support Service for People who Support People with Multiple Sclerosis.

NAME OF PRINCIPAL INVESTIGATOR: (Name of PI)

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to determine if a change in the way in which nurse specialists provide support to people who support people with multiple sclerosis (PwMS) results in better care outcomes for people with a diagnosis of MS and their nominated support pers

ons. .

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in this study because you have been identified as a person who provides support for a person who has multiple sclerosis and the person you support is interested in taking part in this study and has nominated you as their support person. . For the purpose of this study a 'support person' is the person who provides the most emotional or physical support to a person with multiple sclerosis and is not a paid service provider. This person may be a spouse or partner, other family member, carer or friend. You are eligible to participate in this study if you are over 18 years of age, you are not receiving psychiatric care for a diagnosed mental illness and both you and the person you support have discussed and agreed to take part in the study.

The Faculty of Health Sciences Ethics Committee Trinity College Dublin and the Research Ethics Committee in (Name of Hospital)I have given approval for this study to

be carried out. The nurse specialist in your hospital has agreed to participate in this study and your neurologist has given permission to me to write to you and invite you to take part in this study.

WHAT WILL HAPPEN IF I VOLUNTEER?

If you agree to participate, you will have an equal chance of being assigned to either the nurse-led telephone support service (the intervention) or continue with nurse specialist support as you currently receive it.

You will be asked to complete a number of questionnaires on three occasions. You may choose to answer most of these questionnaires via a telephone call from the researcher or fill them in at home and post them back to the researcher using a reply paid envelope that the researcher will provide. Two short questionnaires must be filled in by the researcher and this will be done through telephone contact with you. At the beginning of the study you will be asked to fill in six questionnaires, which should take no longer than 40-50 minutes to complete. The sixth questionnaire is on the services used by the person you support and the results will be used to find out if there are any possible cost benefits to the intervention. You will be asked to consult with him/her in advance of the call or when completing it at home. You will also be asked to keep a record of all health or community care services that you use to help you during the study (for example if you buy in help in the home or receive this service through the health care system). This information will also be used to find out the possible cost benefit or otherwise of this intervention.

Six weeks into the study you will be invited once again to complete five of the same questionnaires. At the end of the study you will be asked to complete the same six questionnaires that you received at the start of the study. In order make sure the intervention was delivered as it was supposed to be, during the final telephone contact with you the researcher will also ask you what help or training you received during the study.

You will receive a pre-notification phone call of data collection one week in advance of the data collection date. Participants whose response questionnaires are not received

within one week of the expected date will receive a reminder letter by post (see appendix 73).

Questionnaires completed by telephone call may be recorded or monitored by a second person to ensure that the researcher is accurately recording the responses. You will be asked if you are still in agreement to have this call recorded prior to recording and should you wish you may have a copy of this recording. Records will be kept of all telephone contact and follow-up care between you and the nurse specialist throughout the intervention and this information will be used in the overall evaluation of the intervention.

If you are in the intervention group, you will also receive a telephone call from the nurse specialist in the neurology clinic where the person you provide care for attends. In preparation for this call you will receive a support person guide book which outlines the process and you are required to read and complete the worksheets in this guide book in advance of the first call from the nurse specialist. It is anticipated that this may take up to half an hour. The nurse specialist will enquire as to how you are getting on, assist you to learn problem management skills, and provide any support, guidance or referral to other services that you may require in order to assist you to provide the best support possible for the person you support and your own wellbeing. You will receive a total of four calls from the nurse specialist over a three month time frame. The length of each call from the Nurse Specialist will depend on the nature of the problems you are exploring and could last between 30-40 minutes. You will receive two calls in the first month of the study and then one call each month for the following two months. In order to ensure that the intervention is delivered as required, the telephone call between you and the nurse specialist may be recorded or the researcher may be present during the call to observe the delivery of the intervention. Your verbal consent to have this call recorded will be obtained prior to recording and, should you wish, you may have a written copy of this recording.

If you are in the intervention group you will also be asked questions about how the intervention was carried out and your satisfaction with the service offered. In addition, in order to determine if there are any possible benefits from this intervention for the people who are supported/cared for, the person you support/ care for will have an

equal chance to all other people with MS who's nominated support person is in the intervention group of being selected to take part in two interviews (one at the start of the study and one at the end of the study), about their experiences of being supported by you.

If the person that you provide care for has difficulty filling in their questionnaires they may ask you for assistance.

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without difficulty. This will not affect your future treatment or that of the person you care for in any way. Furthermore should the doctor of the person you care for decide to withdraw him/her from this study if he/she feels it is in their best interest, you may also be requested to withdraw from the study.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You may not benefit directly from taking part in this study but the information obtained will provide information which will inform nurse specialists as to whether a nurse-led initiative is a more effective way of providing support for carers of people with multiple sclerosis than the approach currently offered. The results may enable nurse specialists determine how they practice in order to provide the best care for people with multiple sclerosis and their nominated support persons.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks associated with this study. However, if you get upset as a result of participating in the study you may contact the researcher who will provide details on how to access support services.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment or that of the person you provide care for, will not be affected in any way.

CONFIDENTIALITY

Your identity will remain confidential. Your name will not be published or linked to any of the information obtained in this study. Each participant will be given a unique study number that is used to identify their data instead of their name. Data collected will be stored with this code number only. Names of participants and their study numbers are kept in a locked filing cabinet in a locked office, as well as in a database that only the researcher can access. This information is stored separately from all data collected. However, there is no absolute guarantee that the information you provide will not be obtained by legal process or court order. Research data may be shared, as required by law, with the relevant (Name of Hospital) authorities. Furthermore, if you give information about the abuse or neglect of a minor or incapacitated adult, or make threat of harm to yourself or others, I am obliged to report this information to the relevant statutory authorities. As a registered nurse I am obliged under the Code of Professional Practice, An Bord Altranais, to report any issues that you may reveal, which could be considered to place the person you care for at risk to the appropriate authority such as the hospital management in which the person you care for attends or their general practitioner.

The data collected will be used for the purpose described in this information leaflet. Unless otherwise specified, test data gathered from this study will be maintained for 5 years.

If you choose to withdraw from the study, you are entitled to take back your approval for the use of your data. To do this, you should contact the researcher in writing. Data that has already been collected will then be destroyed (unless I am obliged under law to disclose it to the relevant statutory authorities, or unless you agree to allow use of the data already collected).

COMPENSATION

Your doctors are insured by virtue of their participation in the clinical indemnity scheme. This study is covered by the standard institutional indemnity insurance of Trinity College Dublin. If taking part in this study harms you, there are no special compensation arrangements. If you suffer harm, then you may have grounds for legal action. Whether you receive any compensation would depend upon the outcome of your legal action.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by Margarita Corry

Will my expenses be covered for taking part in this study? You will not incur any expenses as a result of partaking in this study.

As a token of appreciation for you time and participation in the study a 20 Euro gift voucher will be sent for you, along with the second set of questionnaires to the carers, which will be roughly 6 weeks into the study.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The (Name of Hospital) Research Ethics Committee have reviewed and approved this study.

CONTACT DETAILS

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Margarita Corry who can be telephoned at (insert study dedicated contact number here) or e-mailed at macorry@tcd.ie.

Having read the information outlined above:

Decide if you wish to take part in the study.

Sign the enclosed statement of interest form Or Consent form and

Margarita will make contact with you to discuss the study further

Appendix 27: Categorisation matrixes for content analysis of the interviews

OVERARCHING CODING MATRIC (Based on the Framework for the Process Analysis)		
Criteria	**Descriptor**	**Indicators (comments from participants)**
Insights regarding recruitment	Access to participant contact details Mode of recruitment Reach (extent to which various subgroups of the population are able to participate e.g. people working).	Up-to-date database Views of database vs. OPD recruitment Access to a landline/mobile Quality of the connection Quiet location to accept the call
Contextual factors impacting positively/negatively on intervention and study delivery	Location Access to various subgroups of target population: Characteristics (layout, furniture, ambiance) known to facilitate or hinder treatment delivery. Aspects of social environment that influence implementation of the intervention:	Ease of location for SP/PwMS access to services if required Are amenities are in place for clients requiring assistance (e.g. elevators) NSMS location for doing the interviews Services to be offered by the department or personnel available to support the NSMS (e.g. therapies to refer to e.g.: psychology, occupational therapy, dieticians). Support for the intervention by other health care professionals caring for participating clients
Acceptability of the intervention (Is the	Appropriateness, fairness, or reasonableness	Calls from the nurse specialist Guidebook

intervention including method of delivery acceptable to the participants)	of the intervention	Call schedule Mode: telephone
	Perceived effectiveness of the intervention	Helpful Not helpful Reported negative effects
		<u>Nominated SP</u>
	Risk: potential side-effects of the intervention	Ability to receive the call Barriers to receiving the call Time commitment Lifestyle issues
	Convenience: suitability of the intervention	<u>NSMS</u> Ability to make the calls as scheduled Barriers to making the calls Time commitment Impact on/of their other work commitments
		Views on calling NSMS Satisfaction with the service (CSQ)
	Adherence: willingness to use the intervention	Views on pro-actively calling nominated SPs.

Barriers to delivery of the intervention	Availability & Quality of interventionists	Numbers at each site Holiday cover Sick cover Resignation factors Cover for other life events
	Material resources (availability of all material resources for proper implementation of the intervention)	Equipment (availability of head-sets, recorders). Printed materials e.g. educational booklets, other material for distribution to participants. General supplies e.g. pens.
	Training of interventionists	Content of the training session Clarity Detail Adequate time allocated What might help? Difficulties or challenges in carrying out the activities with specific subgroups of the target population Interventionist level of skill performance of interventionists Interventionists understanding of the core concepts underpinning the intervention

	Fidelity of intervention implementation Ability of nominated SP to participate in the intervention	Ease of delivery of the intervention Extent to which NSMS adhered to the principles of the intervention Impact of unexpected life events Work pattern
Participants recommendations	Areas that participants felt could be improved/changed	Comments for improvement
Satisfaction	Comments on satisfaction Results from Client Satisfaction Questionnaires (CSQ)	Positive comments from nominated SP CSQ results
Participant	**CODING FRAMEWORK**	
Nurse Specialist in MS (baseline)	Issues that SPs present with Type of care provided to SPs Frequency of contact with SPs SPs ability to make contact with NSMS Call back system NSMS perceptions of ability to provide care NSMS view of ideal care Personal characteristics Number of years nursing prior to becoming NSMS Number of years as a NSMS Highest Nursing Qualification	

	Additional modules/courses completed that included communication skills training
Nurse Specialist in MS (Post-intervention)	What it was like to deliver the telephone support intervention *Issues raised by the nominated support persons* *Ability to provide the support required* *Challenges encountered* View on continuing with the support service Suggestions for changes to the intervention *Timing of the calls* *Frequency of calls* *Who it should be offered to* *Newly diagnosed* *All support persons* *Other*
People with MS(Pre-interventions interviews)	SP always able to provide the support needed • Yes • No Barriers to SP providing support Difficulty separating out usual activities from MS supporting Type of support provided by SP Emotional support Able to talk to SP Advice on what to do Barriers to seeking support Emotional support Facilitators of receiving support

	Knowing SP is there SP understands Physical Support Instrumental Personal Financial Support Frequency of receipt of support • Daily • More than once a week • Ongoing • weekly Mutual nature of support Is SP always able to provide the support you need What would help SP to continue provide the support Don't know Knowledge network of support is available Practical help Who is best placed to provide support Other sources of support Value of other support structures Why PwMS nominate the named SP?
People with MS (Post-intervention)	Impact of MS on need for support Length of interview How much support SP provides Frequency

	• Daily • more than once a week • Ongoing • Weekly Emotional support • Able to talk to SP • Advice on what to do • Barriers to seeking support • Facilitator of receiving support • Knowing they are there • Understanding Physical care Instrumental care Personal care Financial support Barriers to SP providing support Difficulty separating out usual activities from MS supporting SP always able to provide the care required? How MS impacts on support needs Mutual nature of support Supports needed to help SP continue to provide support going forward? Don't know Knowing network of support available Practical help

	who is best place to help Pre-post difference More confidence More understanding Responsive Not sure Positive outcome for SP Others for PwMS Difference noted in way support is provided Anything negative Issues that may have impacted on outcome
Nominated Support Person (Post-intervention)	Helpfulness of the calls from NSMS Use of the Guidebook provided Guidebook helpful Guidebook made sense Used the guidebook Adequacy of number of calls More or less calls required Most helpful component of the intervention Suggestions for intervention improvement How now feel about contacting NSMS No change Sooner Experience of being in the study

	Intrusive Time consuming Helpful to be in the study? Why SP took part in the study SP's view of who is best placed to deliver the intervention Any nurse Any NSMS NSMS who cares for PwMS Other member of the team Significant life event during the course of the study

Appendix 28: Study protocol

STUDY PROTOCOL

An Exploratory Randomised Controlled Trial Of A Manualised, Nurse-Led, Telephone Intervention Support Service For People who Support People With Multiple Sclerosis (MNTISS Trial).

Clinical Principal Investigator:

Name of Clinical site Neurology consultant or Nurse

Researcher:

Margarita Corry MSc. BSc. (hons) psychology, BNS (NUI) RNT, RGN, Cert. Neuromedical/surgical nursing, Lecturer in Nursing /PhD student, School of Nursing & Midwifery, Trinity College Dublin.

Academic Supervisors:

Professor Mike Clarke, Director UK Cochrane Centre and Adjunct Professor to School of Nursing & Midwifery TCD

Professor Alison While, BSc MSc PhD RGN RHV CertEd, Professor of Community Nursing, King's College, London.

Professor Joan Lalor Associate Professor in Midwifery, School of Nursing & Midwifery, Trinity College Dublin

Participating Centre: Neurology Department, St. Vincent's University Hospital, Elm Park, Dublin 4.

INTRODUCTION

This protocol is for an exploratory randomised control trial of a manualised nurse-led telephone support intervention. The protocol covers stage 2 and 3 of a three phase study. In phase one of the study, a manualised nurse-led telephone support intervention (MNTSI) was developed and this comprises the intervention to be tested in phase 2. The MNTSI is an innovate and potentially cost effective way of optimizing the use of current health care resources and improving the quality of care for service users. Phase 2 involves the testing of the intervention to determine it potential benefit in terms of outcomes for people with multiple sclerosis (PwMS) and their nominated support persons. For the purpose of this study a support person is defined as a person who provides the most emotional support or physical assistance to a PwMS, and who is not a paid service provider. This person may be a spouse or partner, other family member, carer or friend. Outcomes for PwMS will be determined through their qualitative experiences of receiving care from a nominated support person who participates in the study. Outcomes for support persons of PwMS will be determined as improved support person self-efficacy, preparedness to care, decreased burden and improved quality of life. In phase 3 of the study, a cost effectiveness analysis will be performed to estimate care package costs

AIMS OF THE STUDY

Aim

The primary aim of this study is to determine if a manual based telephone intervention support service for people who support people with MS (PwMS), initiated by nurse specialists who provide care to PwMS, has a positive impact on the lives of PwMS and their nominated support persons. For support persons this impact is determined by measurable self-efficacy (in problem management and obtaining respite) and preparedness to support/care, burden, quality of life, service utilization and satisfaction with the support service. For PwMS this is determined by their qualitative experience of the type of support/care they receive from their nominated support person. A secondary aim is to determine the possible economic benefits of the introduction of such an intervention nationally.

OBJECTIVES OF THE STUDY

The objectives are to:

- Determine if a manualised telephone support intervention for support persons of PwMS, initiated by nurse specialists improves support person self-efficacy (in problem management and obtaining respite), preparedness to support/care and the subjective burden and quality of life (QoL) of support persons of PwMS.
- Determine if a manualised telephone support intervention for support persons of PwMS, initiated by nurse specialists improves the subjective burden and quality of life (QoL) of support persons of PwMS.
- Determine the potential economic benefits of the proposed intervention by measuring PwMS service utilisation.
- Evaluate the fidelity of the implementation of the intervention
- Determine if the nurse-led manualised telephone support intervention for support persons of PwMS results in a qualitative improvement in the experiences of PwMS of the support/care provided by the support persons.
- Describe support persons' experiences of and satisfaction with receiving the nurse-led manual based telephone support intervention.
- Describe the experiences of specialist nurses of delivering the nurse-led manual based telephone support intervention.

HYPOTHESES

Null Hypotheses

There is no difference in self-reported measurable support person self-efficacy, preparedness for supporting/caring, burden and QoL for support persons who participate in a nurse-led manual based telephone support intervention service when compared to support persons who do not participate in the telephone support intervention.

There is no difference in the cost of service utilisation for PwMS whose support persons participate in a nurse-led manual based telephone support intervention for support persons when compared to PwMS whose support persons do not participate in the telephone support intervention.

BACKGROUND

Over 7,000 people are diagnosed with multiple sclerosis (MS) in Ireland, a condition with a

disease progression that is unpredictable in presentation and course, and impacts on an individual from a physical, psychological, social and spiritual perspective in early-mid-adulthood. Despite an increased need for help as the disease progresses, the burden of care falls primarily on the family and unpaid carer. The impact of caregiving on carers of PwMS has been well documented in particular the negative impact upon carers' psychological well-being has been demonstrated across a number of studies (Corry & While, 2009). Carers were found to experience increased caregiver burden and decreased quality of life (Corry & While, 2009). Factors identified as contributing to the burden of care for caregivers include perceived lack of support (Corry and While, 2009), shared health status of the carer and patient (Forbes *et al.* 2007) and decreased caregiver QOL (Bushe, 2008). Alshubaili *et al* (2008) concluded that special attention needs to be given to caregivers if they are less educated, unemployed, caring for patients with longer duration of illness and less education. In particular, carers' fear of having MS and negative attitudes to illness need to be addressed (Alshubaili *et al.* 2008). In addition to the needs of carers in general, the unique needs of spouses of PwMS was highlighted by Corry and While (2009). There is no published literature exploring the burden of care or quality of life (QoL) of people with multiple sclerosis (PwMS) or their carers from an Irish perspective and the literature from an international perspective provides little evidence of the impact of nursing interventions to alleviate caregiver burden and improve quality of life. The need for caregiver support in the Irish context is essential, as two thirds of all carers' own lives are impacted upon by caring responsibilities, and 27% of all carers report high scores on the caregiver strain index (Quarterly National Irish Household Survey, 2009).

There is increasing evidence of a link between caregiver preparedness and caregiver burden. In a study with carers of cancer sufferers (Scherbring, 2002) burden was found to decline by about 17% for every one-unit increase in preparedness. Similarly, Archibold *et al.* (1990) found that preparedness contributed to between 3 and 16% of variance in the predictors of carer role strain in older persons. The importance of caregiver preparedness was recently highlighted by Schumacher *et al.* (2007) who concluded that in order to protect carers from negative caring outcomes, in addition to a good relationship between the carer and care recipient, carers also needed to consider themselves well prepared for the role. Caregiver preparedness in MS has been found to be amenable to intervention. Although few significant findings were reported from the only study on the outcomes of an intervention for carers to meet the challenges of MS (Finlayson *et al.* 2009), the programme was found to improve carers preparedness as identified from the Caregiver Preparedness Scale ($t=-2.51$, $DF=18$, $p=0.02$). Further evidence was found in the qualitative findings where respondents reported increased confidence in their role as carers, feelings of less anger, happier and an awareness of the need to plan and ask for help.

The lack of additional statistical evidence supporting these qualitative findings may be due to the fact that this was a pilot study and therefore used a small sample size (n=19). Other measures identified as ameliorating stress include coping (O'Brien, 1993), feeling appreciated (Wollin and Sato, 2001) and getting support from others, especially friends and relatives (Ybema *et al.* 2002). Interest, support from health professionals, family and friends, access to information, feeling that their own lives are productive, encouragement to keep control over their own lives as well as financial security were among the top 10 needs of significant others of PwMS identified by Koopman *et al.* (2006).

Many carers take on the caring role because of their close relationship with the PwMS (Pakenham, 2008). Family members, usually spouses/partners become carers for PwMS. Partners/spouses usually turn to each other for support. However, becoming a carer provides a new dimension to the relationship, which can leave the caring partner/spouse feeling isolated and unsupported. A recent small scale study (Phelan, 2010, unpublished, accessed via Multiple Sclerosis Society, Ireland (MSI)) found that carers of PwMS in the west of Ireland were not always aware of the support services available to them in the community, for example, what respite services they can avail of or what education/training is available to them on how to provide care for a PwMS. Consequently, they report similar low levels of use of community resources to that reported by carers of PwMS internationally. The findings echo those in an unpublished report from MSI where the need for information was identified and in particular information in relation to medication management.

Nurses caring for PwMS currently provide support to carers if the carer is present during health care contacts or episodes of caregiving to PwMS and on request. However, most carers only avail of this support when in a crisis and in severe distress (personal communications, Nurse Specialist in MS, 2009) with the number of carers not using this support unknown. NSMS work closely with neurologists, care workers from MS Ireland, psychologists and other members of the multi-disciplinary team attending the neurology clinic. They have specialised knowledge in caring for PwMS and their carers and the management of symptoms of MS, and are well positioned to provide specialist support, information and referral. Much of the unique support given to carers of PwMS by MS nurses in Ireland is undocumented so that their impact upon patient and carer outcomes is unknown.

The well-being of carers of PwMS is crucial with limited budgets resulting in increased reliance upon carers to provide ongoing support for PwMS. Health care professionals need to prioritise health promotion, information giving and pro-active management of situations among carers of PwMS if the deleterious effects of care-giving on the PwMS and their carers are to be minimised

and poor health avoided. The survey carried out by MSI and the findings from a small scale survey with Irish participants by Phelan (2010, unpublished) highlight that carers have unmet needs that fall within the scope of nursing. Some carers don't know where to seek this support, may feel uncomfortable asking for help and may not have the necessary skills and knowledge to know what information or support they require, and whom to approach despite the evidence of substantial need (Corry & While, 2009).

A search of the literature revealed that no published studies exist on the use of telephone support interventions for caregivers of PwMS. In the area of chronic illness one study was found evaluating the impact of a social problem-solving telephone partnership on primary family caregiver outcomes (Grant *et al.* 2002) and this study provided evidence to support its use. However, the extent to which telephone support interventions have been used in an attempt to support carers is evident from the number of studies found on carer telephone support in areas including Dementia (n=9), Traumatic brain injury (n=1), HIV (n=2), Cancer (n=3), Older adults (n=3), Hospice (n=1) and mixed carer groups (n=9). A variety of designs including randomised controlled trials (RCTs), pilot RCTs, surveys and qualitative studies have been employed to evaluate the interventions. The findings reveal that the telephone as a medium for providing carer support has been delivered to carer groups or individually, or using a combination of groups and individual contacts. Although interventionists were nurses in six and a combination of nurses and other health care workers in two studies, few of the studies specifically focused on interventions taking cognisance of the scope of nursing practice, in particular the contribution and scope of practice of nurses on the general register. The range of care recipients, research designs and objectives for the studies on carer telephone interventions make it difficult to draw definitive conclusions regarding particular outcomes and interventions. However, positive findings can be categorized as feeling supported (Bank *et al.* 2006, Stewart *et al.* 2001; Salfi *et al.* 2005), feeling empowered (Wilkes *et al.* 2004; Stewart *et al.* 2001), reduced carer burden (Bormann *et al.* 2009; Tremont *et al.* 2008; Stewart *et al.* 2001) and others, such as reductions in perceived depression (Stewart *et al.* 2001; Walsh and Schmidt, 2003; Bormann *et al.* 2009), improved quality of life (Bormann *et al.* 2009), reduced despair, and disorganisation despite a worsening in the care recipient condition (Walsh and Schmidt, 2003), a significant reduction in stress (Bormann *et al.* 2009), decreased depression, increased life satisfaction (Davis *et al.* 1998) and perceived helpfulness such as sharing thoughts and feelings, expressing feelings of being overwhelmed, discussing physical and psychosocial problems, forgetting the situation, seeking reassurance, asking for information (Chang *et al.* 2004).

The positive findings from the studies on telephone support interventions, along with the current use of family member/carer telephone contact with NSMS when in crisis, suggest that a nurse

specialist proactive approach to problem management, information and advice giving has potential for positive outcomes for nominated support persons of PwMS.

STUDY DESIGN

An exploratory study using a randomised controlled trial, based on the Medical Research Council Framework for design and evaluation of complex interventions to improve health (Campbell *et al.* 2000) is the design most appropriate to address the study hypotheses, using an intervention and control group. The hypotheses are designed to test if the intervention causes a measurable change in terms of support person/carer preparedness, QoL, burden and service utilisation.

A mixture of both quantitative and qualitative methods will be used for data collection and analysis.

A qualitative exploration of the experiences of the nurses providing the telephone support intervention and their views as to who is best placed to provide this service on an ongoing basis will be carried out.

Sample

For the purpose of this study a support person is defined as a person who provides the most emotional support or physical assistance to a PwMS, and who is not a paid service provider. This person may be a spouse or partner, other family member, carer or friend.

A preliminary power analysis was conducted to assess the required sample size and was based on the Support person Preparedness Scale which consists of 8 questions using a 4 point scale ranging from 1 to 4, with a score of 1 representing 'not prepared at all' and a score of 4 representing 'very well prepared'. Based on an alpha level of 0.05, a power level of 80% and a previously reported effect size of 0.55 (Finlayson *et al.* 2009), the required sample size without loss of any follow up would be in the region of 53 participants per group, for a one-tailed (directional) hypothesis. A minimum sample size of 100 participants in each of the intervention and control group was decided upon to allow for inevitable sample attrition. As there is a relative small number of people with MS registered at any site and there is no database of support persons it is not possible to be sure that all those invited will fulfil the inclusion criteria. Therefore in order to be able to evaluate the intervention recruitment will continue for the duration of the study until the required sample size has been achieved. This will allow for inevitable non-response/non agreement to participate in the study.

Inclusion/Exclusion Criteria

Inclusion Criteria

PwMS:

- People who have a diagnosis of Multiple Sclerosis and are > 18 years of age.
- PwMS who nominate a support person.

Support persons:

Spouses, partners, other family members, carers or friends nominated by PwMS who do not have a serious mental health problem.

Nurses:

- Nurse Specialists caring for PwMS and their nominated support persons in two-three who agree to take part in the study.

Exclusion Criteria

For PwMS:

- PwMS who cannot nominate a support person.
- PwMS who are already engaged in similar research

Recruitment and entry to the trial

Nurses

- Nurse specialists caring for PwMS and their nominated support person in two-three specialised neurological centers in Ireland will be invited to partake in the study on a voluntary basis.

PwMS and nominated support persons

- Based on attendance, PwMS and their nominated support persons will be recruited, via the neurology clinics.
-

The unit of randomisation will be the individual within each treatment centre. Support persons who consent to partake in the study will be randomly assigned to either the control or intervention group on a 1:1 intervention to control basis. The randomisation sequence will be carried out by a statistician and held by a third party and research sponsor (Prof. Mike Clarke) who will inform the researcher of the randomisation process following consent and baseline data collection. The statistician and Prof. Clarke will only hold the randomised numbers and inform the researcher as to which group a unnamed participant is assigned. They will not have access to participants name or any other information about the participant. In addition to this measure, the support persons in this study are not known to the researcher and there is therefore no reason why the researcher may wish to allocate participants to one arm of the intervention over the other. PwMS will not be randomised as they are not receiving the intervention.

The 15 PwMS whose support person participates in the intervention will be randomly selected for interview using systematic random sampling i.e. every nth person will be invited until the required sample is achieved.

The intervention

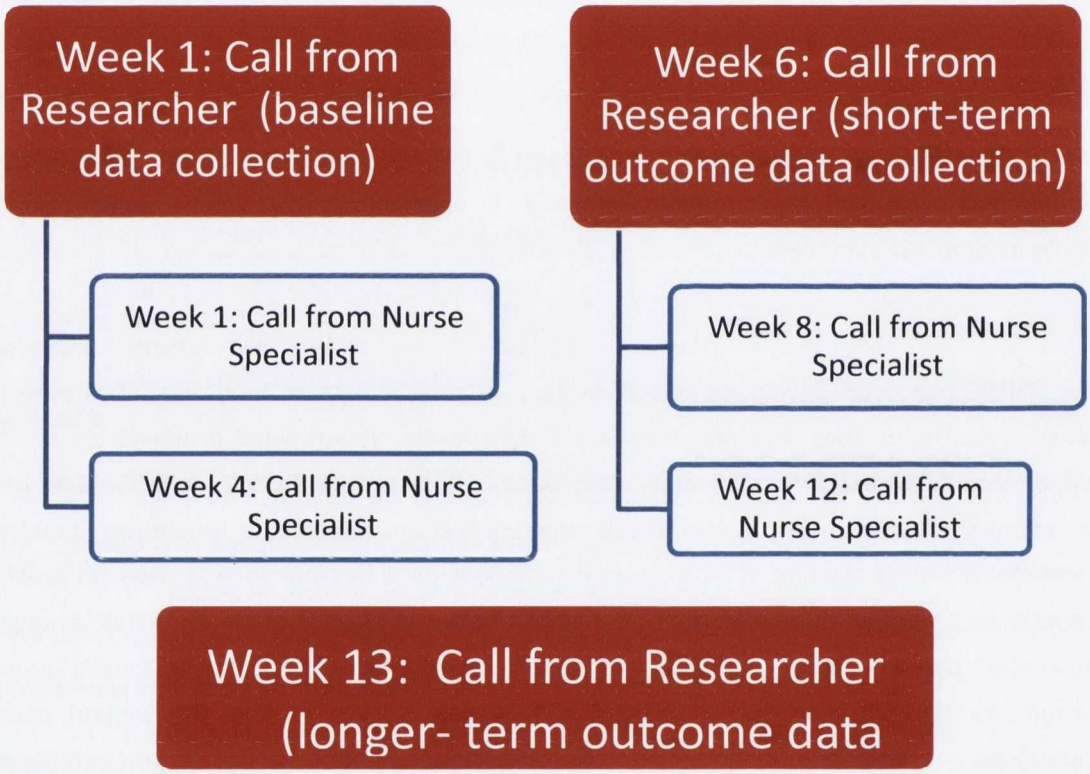
The MNTIS has been developed based on support person support needs identified from the literature and interviews with neurology nurse specialists. The manual is based around the support that nurse specialists currently offer to support persons of PwMS regarding their need for information and nursing therapeutic intervention in relation to managing problems encountered with caregiving. Three theoretical models guide this intervention. Two are problem management models. Egan's Model of the skilled helper is used to guide the nurse in helping the support person manage problems and identify opportunities. The Prepared Family Support person Model of Problem-solving (The COPE Model) is used to help the support person understand and work through the process of problem management. Finally, support persons are enabled to learn problems management and opportunity development skills using an experiential learning approach.

Although the NSMS telephone call will follow the manual guidelines on how to approach the telephone support, it is primarily a support person problem management and resource manual, and each support session will be individualised based on unique needs of the support persons and professional nursing judgement.

The intervention group will receive a nurse initiated telephone call inquiring after their well-being and help in managing problems they are encountering with caregiving. They will receive two

calls during the first months followed by one call at monthly intervals for the following two months (4 calls over 3 months). The nurse will be guided by a manual. The support persons will be able to contact the nurses at other times in the normal way, including leaving messages on the answering machine. The nurses will maintain a log of their contact with support persons using a structured schedule specially developed for this study. The nurses will be requested to record potential improvements to the manual.

Figure 1: Calling schedule to support persons throughout the intervention



Fidelity of implementation of the intervention

During the testing of the intervention, the fidelity of the implementation of the intervention will be evaluated using the 5 elements of the treatment fidelity guidelines introduced by Bellg *et al.* (2004).

Minimising and monitoring contamination: Although the risk of contamination exists in this study, the risk is reduced by the fact that the intervention group is proactively contacted by the NSMS at defined time points, while the control group will not be contacted at all by the NSMS. The control group will only avail of the NSMS support if they request it, as per usual care. Inadvertent contamination is unlikely because of the design of the intervention, and the fact that the support persons in the control group will not have access to the support person guidebook. In addition, during intervention training the NSMS will be advised to revert to their usual approach to providing support to cares for the control group and not to use the steps outlined in the intervention manual. Although the risk of contamination still exists due to the practicalities of implementing this intervention in practice, the above measure will minimize its impact and its continued presence will provide further evidence of the value of the intervention, when significant results are reported by the intervention group.

Training is standardised and interventionists require and maintain the skills to competently deliver the intervention: A training package has been developed as part of the manual and this will be used for training any interventionist who may be involved in delivering the intervention. The interventionist training plan will be devised based on the model guiding the study and the expected outcomes. In addition, 10% of all telephone calls will be recorded and reviewed for adherence to the stages and underpinning theory of the model.

Standardisation and monitoring of the intervention: A standard protocol for the delivery of the intervention will be developed as part of the manual and interventionists will be required to adhere to this protocol. Adherence to the protocol will be determined through monitoring of recorded telephone contacts, analysis of written notes from telephone contacts and using semi-structured interviews with relevant stakeholders including support persons, PwMS and nurses specialists.

Process to monitor and improve the ability of recipients to acquire knowledge and skills from the intervention: the outcomes of the pilot phase of the study will be monitored for improvement in support persons' perceptions of preparedness to care. Areas of weakness will be identified and strategies will be implemented as part of the intervention to improve support persons' ability to benefit from the intervention as appropriate.

Monitor and improve the ability of participants to use the skills: This will be achieved by ongoing assessment of participant progress at each NSMS telephone contact. NSMS will be instructed to monitor their written notes for support persons' progress.

Data Collection Tools

Tools for use with PwMS

- Multiple Sclerosis Impact Scale (MSIS-29 (Hobart *et al.* 2001).
- Data on QoL for PwMS will be collected using the Multiple Sclerosis Quality of Life (MSQOL-54) questionnaire.
- A structured interview guide will be used to evaluate PwMS's experiences of informal support/care prior to and following the nurse-led intervention.

Tools for use with support persons

These tools have been decided upon because of their relevance to the scope of nursing practice, their prior use with this population, psychometric properties and appropriateness to measuring outcomes for the proposed intervention.

- Support person self-efficacy for obtaining respite and problem-solving
- Support person Preparedness: This will be measured using the 'Support person preparedness scale', (Archibold *et al.* 1990).
- Support person quality of life: WHOQOL BREF instrument (WHOQOL BREF) (WHO, 1996)
- Support person burden: Support person Reaction Assessment (CRA) (Given *et al.* 1992) and the Bakas Caregiving Outcomes Scales (BCOS) (Bakas *et al.* 2006).
- Satisfaction with the telephone support intervention: Client Satisfaction Questionnaire-8
- A structured telephone interview guide will be used to evaluate the support persons' experiences of the telephone support intervention and how it could be improved on to better meet their needs.
- A semi-structured interview will be conducted with nurse specialists to explore their experiences of providing the telephone support intervention.

Tool for the cost effectiveness analysis

- The MS-specific Client Socio-demographic and Service Receipt Inventory (MS-CSRI) The MS-CSRI is a newly developed UK tool, with unknown psychometric properties. Validity and reliability for use in this study will be determined as part of pilot work.
- Support person record of health and community care services used during the study to help them manage supporting a person with MS.

Outcome data will be collected at baseline, 6 and 13 weeks. Any changes observed at 6 weeks will be considered as short term outcomes while those at 13 weeks will be considered longer term.

Week 1: Baseline data collection (Both intervention and control)

PwMS; *The Multiple* Sclerosis Impact Scale (MSIS-29) and *MSQoL-54.* For PwMS who may have difficulty completing the form assistance will be provided by the support person or researcher if required and requested.

Fifteen PwMS in the intervention group will be invited for interview on their experience of receiving informal care

Support persons:

Support person preparedness scale, Support person Reaction Assessment (CRA), Bakas Outcome Scale, and WHOQOL BREF. The questionnaires will be distributed during attendance at the clinic and a reply paid envelope provided. Participants will be able to complete the questionnaires on site and leave them in a box provided or take them home and post them using the reply paid envelope.

Support persons will also receive a MS specific CSRI questionnaire for completion with the PwMS.

Time 1: Week 6 (Both intervention and control)

Support person Preparedness scale, Support person Reaction Assessment (CRA) and Bakas Outcome Scale, and WHOQOL BREF. The questionnaires will be distributed by post and a reply paid envelope provided. Alternatively, participants will be able to leave the questionnaires in a box provided in the neurology clinic if they are scheduled for an appointment.

Time 2: Week 13 (Both intervention and control)

Support person Preparedness Scale, Support person Reaction Assessment (CRA) and Bakas Outcome Scale, WHOQOL BREF and CSQ-8. The questionnaires will be distributed by post and a reply paid envelope provided. Alternatively, participants will be able to leave the questionnaires in a box provided in the neurology clinic if they are scheduled for an appointment.

Support persons will also receive a phone call from the researcher thanking them for their participation in the study, reminding them to return the postal questionnaires and to collect CSSRI data.

Support persons in the intervention group will be invited to participate in a short telephone interview exploring the acceptability of the intervention.

The nurse specialists will be invited to be interviewed regarding their experiences of delivering the intervention.

PwMS: The fifteen PwMS who were interviewed at baseline will be invited for interview on their experience of receiving informal care during the 12 weeks of the intervention

PwMS baseline data

	Baseline	Time 1(week 6)	Time 2 (week 13)
Multiple Sclerosis Impact Scale (MSIS-29	√*		
Multiple Sclerosis Quality of Life (MSQOL-54) questionnaire	√*		
Structured interview to determine experiences of informal care prior to the intervention.	√**		
Structured interview to determine experiences of informal care following the intervention.			√**

* intervention and control **intervention only

Support person outcome data collection points

	Baseline	Time 1(week 5)	Time 2 (week 13)
Support person self-efficacy	√*	√*	√*
Support person preparedness scale	√*	√*	√*
WHOQOL BREF instrument (WHOQOL BREF)	√*	√*	√*
Support person Reaction Assessment (CRA)	√*	√*	√*
Bakas Caregiving Outcomes Scales (BCOS)	√*	√*	√*
Client Satisfaction Questionnaire-8			√**
Support person structured interview guide			√*
Support person diary (record of services used during the study)			√*

* intervention and control **intervention only

NSMS data

	Post-delivery of the intervention
Semi-structured interview	√

DATA ANALYSIS

Quantitative data will be analysed at two levels of complexity (descriptive and inferential), using an intention to treat approach. Data will be entered onto a computer software data analysis package such as SPSS-16. Data entered will be checked and cleaned.

The descriptive and inferential analysis will involve the following:

Establishment of baseline impact of MS and QoL for PwMS. This will enable the researcher to contextualise the support role and perform both within and between group comparisons on support person data.

Establishment of baseline, time 1 data and time 2 data to determine support person preparedness, burden and quality of life to allow comparisons between the treatment and control groups.

Within group analysis. This analysis will examine the support person preparedness, burden and quality of life within the treatment or control group, within genders and age and possibly within severity of impact of MS on PwMS. Possible appropriate techniques include: basic descriptive statistics, more detailed statistics for non-categorical data such as t-tests and analysis of variance.

Between group analysis. In order to evaluate outcomes it is essential that between group comparisons be made. However members of different groups may exhibit different baseline figures. It is envisage that the change from baseline figure be examined using the t-test and analysis of variance as appropriate.

Cost effectiveness analysis will be based on the cost of the intervention and the cost of services used. Service utilisation will be costed by unit and the intervention in terms of MS nurses' time and call costs. Cost effectiveness analysis will be done by establishing the cost of the services used by PwMS at baseline and on completion of the study (Time 2 data collection). The data from the two groups will then be treated in a similar manner to that outlined above. Following descriptive analysis tests of difference will be used to determine the differences in costs of services used by the two groups.

Thematic content analysis will be used for the qualitative data.

ETHICAL ISSUES

The ethical conduct of the study will adhere to the ethical principles of beneficence, non-maleficence, automony, justice, anonymity and confidentiality and will comply with all ethical guidelines and standards pertaining to research with human subject. Ethical approval will be obtained prior to commencement of the study.

RESOURCES

Health Research Board Funding has been secured. This provides a contribution to the researcher's salary for three years and a contribution to the running costs. All additional costs will be provided by the researcher (Margarita Corry).

TIMELINES

The pilot study is expected to commence in April/May 2010 following completion of expert intervention manual review. The main study is expected to commence in October 2011 and data collection is planned over a 2 year period with a final study completion date of September 2014.

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Appendix 29: Ethical approval from Trinity College Dublin

TRINITY COLLEGE FACULTY OF HEALTH SCIENCES

Trinity College, Dublin 2, Ireland
Tel: +353 1 896 1476
Fax: +353 1 671 3956
email: medicine@tcd.ie

Professor Dermot Kelleher, MD, FRCPI, FRCP, F Med Sci
Head of School of Medicine
Vice Provost for Medical Affairs

Ms Fedelma McNamara
School Administrator
email: medschadmin@tcd.ie

Ms Margarita Corry,
School of Nursing & Midwifery,
24 D'Olier Street,
Trinity College,
Dublin 2

Monday, 17 May 2010

Study: An Exploratory Randomised Controlled Trial of a manualised, Nurse-Led, Telephone Intervention Support Service for Carers of People with Multiple Sclerosis.

Dear Applicant (s),

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in March 2010, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely

pp Siún Healy

Prof. Orla Sheils
Chairperson
Faculty of Health Sciences Ethics Committee

Cc
Prof Catherine Comiskey,
Dr Elizabeth Curtis,
School of Nursing & Midwifery,
24 D'Olier Street,
Trinity College,
Dublin 2

FW: Ethical amendment appllication form for 7th Jan 2010 (Mar 10)

Eimear Mealy <CASEYEI@tcd.ie> 17 January 2011 at 10
To: Margarita Corry <macorry@tcd.ie>
Cc: Eimear Mealy <CASEYEI@tcd.ie>

Dear Margarita,

The Chair has approved your amendment request.

Thank you,

Eimear

Eimear Mealy

Senior Executive Officer

School of Medicine

Chemistry Building

Trinity College

Dublin 2

MYZONE Trinity College Dublin

Margarita Corry <macorry@tcd.ie>

FW: ethical amendments

Eimear Mealy <CASEYEI@tcd.ie> 6 May 2011 10:09
To: Margarita Corry <macorry@tcd.ie>

Thanks Margarita. Your request is approved.

Eimear Mealy

Administrative Officer

(Support to School Administrator)

School of Medicine

Chemistry Building

Trinity College

Dublin 2

Ph: + 353 1 896 1727

Fax. +353 1 671 3956

Email: eimear.mealy@tcd.ie

Web: www.medicine.tcd.ie/

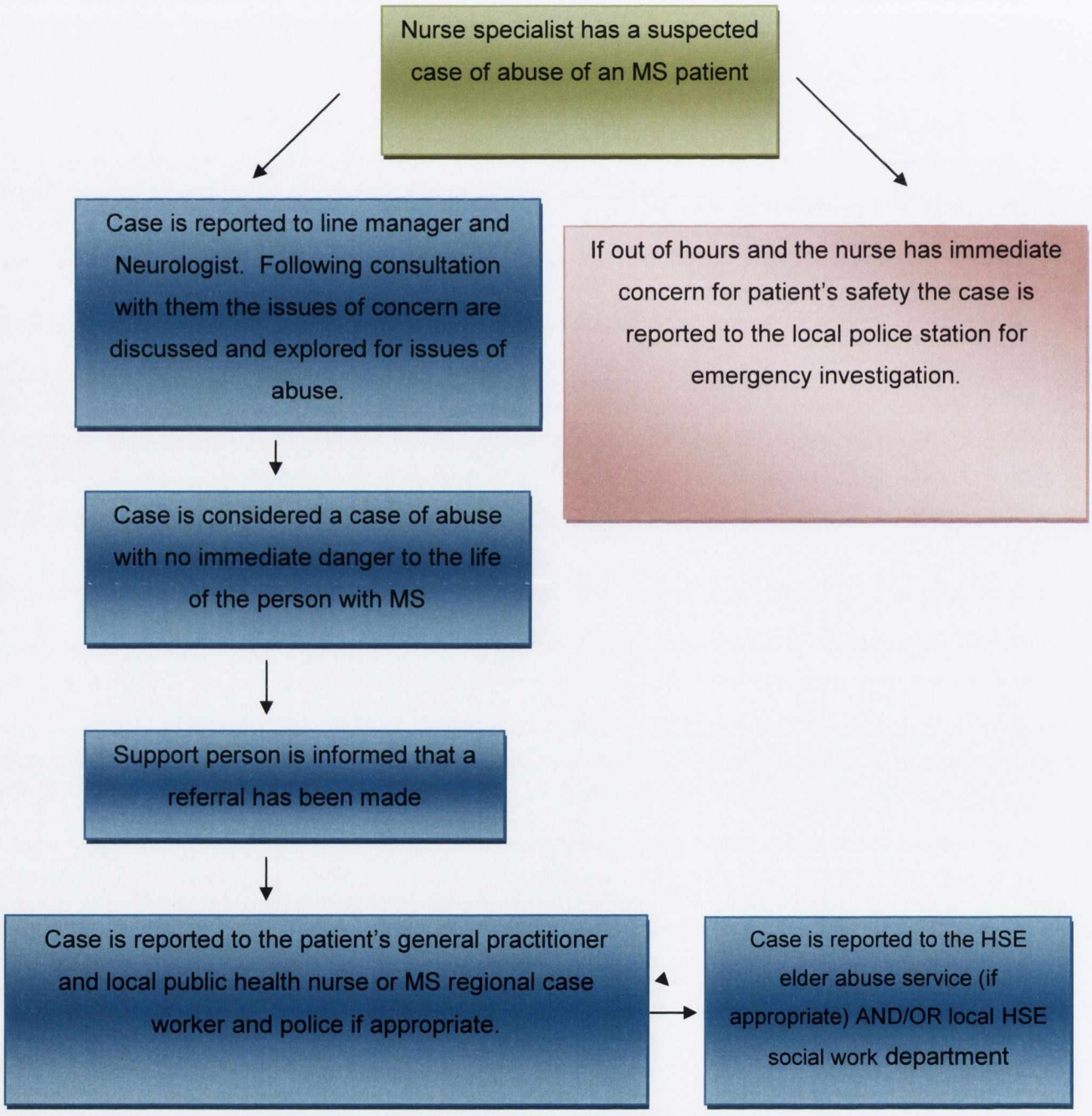
From: Margarita Corry [mailto:macorry@tcd.ie]
Sent: Thursday, May 05, 2011 12:54 PM
To: Eimear Mealy
Subject: Re: FW: ethical amendments

[Quoted text hidden]

Appendix 30: Protocol for suspected cases of abuse

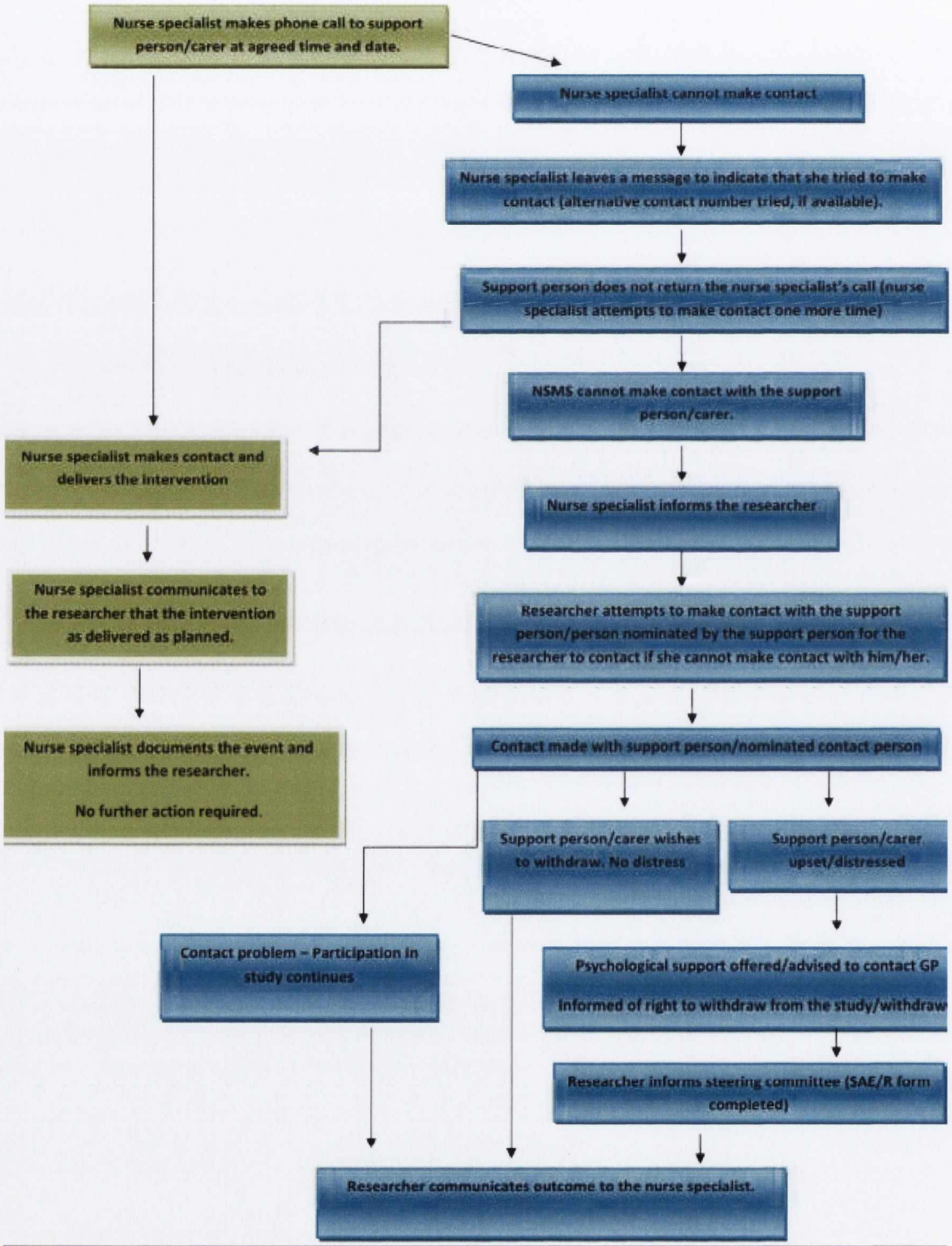
PROTOCOL FOR SUSPECTED CASES OF ABUSE:

In the event that the nurse specialist or the researcher suspects a case of abuse the following protocol will be followed



Appendix 31: Protocol to deal with non-response to intervention calls

Nurse Specialist Flow Chart for Support person/carer contact



Appendix 32: Publications and presentations arising from this study

Peer reviewed publications

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