

An assessment of the feasibility and utility of the MS Symptom and Impact Diary (MSSID)

Joanne Greenhalgh

Health Care Practice R&D Unit, Allerton Building, University of Salford, Frederick Road, Salford M66PU, UK (E-mail: j.greenhalgh@salford.ac.uk)

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Abstract

The Multiple Sclerosis Symptom and Impact Diary (MSSID) was developed to provide a more comprehensive assessment of the impact of multiple sclerosis (MS) on HRQoL for use in clinical practice. This paper reports on an assessment of its feasibility and utility in two outpatient samples of people with MS ($n = 13$ and $n = 63$) using quantitative and qualitative methods. The response rate in study 2 was 82% and 83% of days were fully completed. Most respondents found the MSSID easy to understand and got into the habit of completing it. Missing items increased over time and those who experienced a relapse had more missing items than those who did not but there was no difference in the number of missed days. Some respondents found completing the MSSID enabled them to manage their lives more effectively and provided useful information to their neurologist. It is concluded that the MSSID is feasible for people with MS to complete and some may find the MSSID helpful as a tool to monitor their condition. Further research is needed to examine clinicians' perceptions of the feasibility and utility of the MSSID within clinical practice.

Key words: Feasibility, Multiple sclerosis, Qualitative, Symptoms, Utility

Introduction

The Multiple Sclerosis Symptom and Impact Diary (MSSID) was developed to measure the variability in the day to day symptoms and impact of multiple sclerosis (MS) and has been found to be reliable, valid and responsive to change [1, 2]. It was developed for use in clinical practice in response to observations from patients and clinicians about the difficulties of monitoring MS within clinical practice.

Firstly, people with MS experience considerable day to day variation in symptoms and their impact that were not currently captured by existing instruments [3–5]. People with MS reported finding it difficult to 'average out' their symptom experience even over a period of a week to answer single point health related quality of life (HRQoL)

measures. Secondly, people with MS (in the UK at least) see their neurologist once every 6–12 months and often find it hard to remember the problems (for example, worsening of symptoms) experienced in the intervening time [6].

The MSSID was developed as a way of assisting both people with MS and clinicians to monitor the symptoms and impact of MS more effectively. Respondents complete a total of 33 items each day that are divided into 8 questions, which ask about the severity of MS symptoms and the impact of MS overall on respondents' activities. The MSSID forms three scales that measure mobility, fatigue and the overall impact of MS [1].

As a measurement tool, the use of diaries can have both costs and benefits to the quality of the data collected compared to the use of single point HRQoL questionnaires [7]. This is

particularly important for people with MS whose symptoms may militate against the completion of daily questionnaires. Their use as a tool for monitoring symptoms within clinical practice would also be enhanced if people with MS themselves found diaries useful to complete. Before the MSSID can be put forward for use within clinical practice, evidence to support the feasibility and utility of its completion by people with MS is required.

This paper reports on an evaluation of the feasibility of the MSSID in terms of response rates, missing items and respondents' views, and an exploration of respondents' perceptions of the utility of completing the MSSID.

Acceptability of diaries

Few studies have explored the feasibility of using diaries to measure HRQoL in clinical practice; most have focused on their use in randomised controlled trials. Although many have reported response rates in excess of 80% [8–11], others have reported that completion rates vary from 25% to 91% between centres [12]. Response rates appear better where some form of respondent monitoring takes place, either through telephone reminders, personal pick-up of the diary at the end of the study, or discussion of the results with respondents [12, 13]. Respondents' views of the feasibility of diary completion have also been positive in the few studies to explore this [14, 15]. Overall, these studies suggest that, with some degree of respondent monitoring, diaries are a feasible method of measuring HRQoL.

Threats to the validity of diary data

The most significant threats to the validity of diary data include attrition bias, retrospective completion, sensitisation and fatigue. Attrition bias occurs when those who fail to complete diaries systematically differ in the construct of interest to those who do complete diaries. Attrition bias does not appear to be a problem when diaries are used by the general population [13] but in clinical populations, those with more severe disease are less likely to complete diaries [12].

Retrospective completion refers to when respondents may not complete diaries during the allocated day or time but retrospectively complete the diaries, introducing the possibility of recall bias [16, 17]. The quality of diary data can be improved by adequate instructions that tell respondents what to do when a day is missed and the use of time coded electronic diaries [16, 17].

Sensitisation and fatigue refer to changes in the reporting of events during the diary study. At the beginning of the study, completing a diary may make respondents more aware of their symptoms, and result in increased reporting. This effect may be temporary or persistent. As time goes on, respondents may tire of completing diaries and report symptoms or events less systematically, resulting in a decrease in reporting or increases in missing items [13, 18]. However, these effects may not be large, with most indicators dropping between 5% and 25% over a 2–3 month period [8].

Advantages of diary data

Most health diary studies have focused on the advantages of diaries as a measurement tool for the researcher and the qualities of the resulting data. In this regard, diaries are valuable in understanding symptom patterns and in detecting fluctuations or cyclical changes in HRQoL over time, for example, in response to chemotherapy [12, 19]. Fewer studies have considered the utility of completing a diary from the perspective of the respondent. In this respect, the process of writing a diary can provide respondents with an outlet to their emotions, and can be a useful monitoring tool that enables them to gain more insight into their condition [20–23]. Diary completion is one component of educational interventions that aim to help people with cancer to manage and cope with their pain [24]. However, few studies have specifically interviewed respondents about their experiences of completing a diary, suggesting a need for this kind of approach.

Methods

We evaluated the feasibility and utility of the MSSID using both quantitative and qualitative

methods in two sequential, interrelated studies, as part of the development of the MSSID and an evaluation of its psychometric properties. These studies aimed to examine: [1] threats to the validity of MSSID data in terms of attrition bias, retrospective completion, sensitisation and fatigue; [2] the feasibility and acceptability of completing the MSSID; and [3] the utility of completing the MSSID to respondents. A mixed methods approach was used by combining an analysis of response rates and missing data with an exploration of respondents' views and experiences to provide a more comprehensive assessment than any one method alone.

Inclusion and exclusion criteria

Neurologists recruited participants from outpatient clinics in one (study 1) or two centres (study 2). People with MS attending the clinic were eligible if they were diagnosed with MS, aware of their diagnosis and aged between 18 and 65. We excluded people with significant cognitive impairment who were unable to complete a questionnaire, but people with impaired vision and hand function were included. Those who had been diagnosed with MS for less than 1 year and those who were judged by the clinician to be experiencing difficulties dealing with their diagnosis were also excluded to avoid the possibility of causing undue distress.

At recruitment, clinicians classified MS course for each participant using established criteria [25] and the researcher classified ambulation status for each participant, based on their ability to move indoors on the day of recruitment. Each study was approved by the relevant Local Research Ethics Committees. Once neurologists had introduced the study to participants, the researcher met with participants to gain written informed consent to take part and to explain how to complete the diary.

Study 1

We instructed 14 participants to keep the diary consecutively for 14 days, starting on the day of the clinic visit. All participants were interviewed within a week of completing the diary to explore their views on the diary's feasibility and utility. We asked participants how practical they had found

the diary to complete, what difficulties they had encountered, and how they had addressed these. We also asked participants whether they had found completing the diary useful and what impact completing the diary had on their psychological well being.

The interviews were semi-structured and the participant determined the order of topics discussed, but the interviewer (JG) ensured that the same topics were addressed across participants using a topic guide. Interviews lasted between 30 and 45 min and were tape recorded and transcribed.

Study 2

Of 177 people with MS that met the inclusion criteria, 77 (43%) agreed to take part in the study. We asked participants to complete three diaries consecutively, each covering a four week period (12 weeks, 84 days in total). At the end of 12 weeks, participants also completed a questionnaire specifically designed to examine the feasibility and utility of the MSSID.

We transformed the main themes that emerged from the interviews from study 1 into 12 attitude statements relating to the feasibility (five items) and utility (seven items) of the diary (see Table 1). We asked participants to indicate the extent to which they agreed or disagreed with these statements on a four point likert scale. We also included three additional yes/no questions that asked participants: (1) whether they had needed any help to complete the diary; (2) whether they had ever read back over the diaries during the study; and (3) whether they had found this helpful. Participants were also asked to indicate whether they had experienced a relapse during the study.

To maximise response rates, all participants who returned a diary at the end of month 1 were telephoned once during the study to check whether they were happy to continue to complete the diary and address any problems they were experiencing. Those who did not return a diary at the end of month 1 were not telephoned, as their non response was taken as an indication that they no longer wished to participate in the study, and these participants may have perceived a telephone call as coercion.

Table 1. Attitude statements used in study 2*Feasibility*

- A. I had difficulty remembering to fill in the diary every day
- B. Having to write made filling in the diary difficult for me
- C. I got into the habit of filling in the diary every day
- D. I thought the questions in the diary were easy to understand
- E. I thought the questions in the diary were easy to answer

Utility

- F. Filling in the diary has helped me cope with my symptoms better
- G. The information in the diary would be useful for my neurologist
- H. Filling in the diary made me think more about my symptoms than I would like
- I. Filling in the diary has not told me anything new about my symptoms
- J. I thought the questions in the diary were relevant to me
- K. Filling in the diary has helped me to recognise my symptoms better
- L. Overall, filling in the diary has been useful for me

*Analysis**Attrition bias*

We assessed attrition bias in two ways. First, we analysed the reasons participants gave for dropping out of the study to identify whether any of these were related to the respondent's MS. Secondly, we compared the average number of missing items (the total number of items to complete per participant was 2772), fully incompleting diary days (none of the 33 items completed), partially completed days (some but not all 33 items completed), and fully completed diary days (all 33 items completed) between those who did and did not have a relapse, those who did and did not use a walking aid, and those with relapsing remitting or benign vs. those with progressive MS.

Fatigue

We evaluated whether fatigue occurred by testing whether the number of missing items increased over time. We calculated three missing item indicators for each of the three diary periods: the mean number of missing items (between 0 and 2772); the mean number of fully incompleting days (between 0 and 84); and the mean number of fully completed days (between 0 and 84). One respondent who received the second diary late due to an administrative error was removed from this analysis.

Sensitisation

We explored whether sensitisation occurred by testing whether the reporting of 14 symptoms in

Question 1 (Did you experience any of the following problems as a result of your MS today?) decreased over time. For each diary period, we calculated the average percentage of symptoms reported per day, using the total number of valid (i.e. non-missing) responses as the denominator to control for the effect of missing items.

Feasibility and utility

We examined feasibility and utility in two ways. First, we conducted a qualitative analysis of participants' views of the diary from the interviews conducted in study 1. Second, we analysed the responses to the questionnaire completed at the end of study 2. We explored whether attitudes to completing the diary were different between groups likely to have greater disability, as defined by clinical course (those with relapsing remitting and benign MS vs. those with progressive MS), ambulation status (those who walked unaided vs. those who did not), and relapse status (those who experienced a relapse during the study and those who did not). We also examined whether there were any sex differences in attitudes towards completing the diary, as women are more likely to be diagnosed with MS than men.

Descriptive data indicated that, in nine out of 12 attitude statements, less than 10% of respondents used the 'strongly agree' or 'strongly disagree' response options. We therefore decided to collapse the statements into dichotomous variables to give a clearer picture of those who did or did not agree

with the statements, rather than reporting average scores for the statements.

Retrospective completion

We based our analysis of retrospective completion on participants' reports of their approaches to completing the diary within the interviews in study 1. A theme that included participants' reports of actions taken when they had missed a day was described as retrospective completion.

Statistics

We analysed all data using SPSS ver 9. To examine trends over time in the missing item indicators and total number of symptoms reported, we used a univariate analysis of variance with a linear polynomial contrast, with diary number as the contrast variable. We assessed differences between clinical groups in the missing item indicators and attitude statements using the χ^2 test for dichotomous data and the Mann Whitney *U* test for continuous data, and we set the significance level at $p < 0.05$.

Qualitative

We analysed all interview data and written responses to open ended questions together using Framework [26]. This is a pen and paper method of qualitative analysis that involves three steps: (i) developing a thematic framework to order and

manage the data; (ii) summarising the data; and (iii) abstracting and interpreting the data. We used this technique to generate themes describing participants' views of the feasibility and utility of the MSSID.

Results

Attrition bias: sample characteristics, response rates and missing items

In study 1, 13 out of 14 (93%) participants both completed the diary and took part in an interview. As reported previously, in study 2, 63 of 77 (82%) participants returned all three diaries and were classed as responders and used in subsequent analyses (Table 2) [1]. Of these, 50 (79%) completed all the attitude statements and 61 (97%) reported whether they had experienced a relapse during the study. Twenty-two respondents (35%) provided written responses to the open questions about completing the MSSID at the end of study 2.

Five people (7%) did not return any diaries and, as they were not contacted, the reason for their nonresponse could not be identified. Of those who returned either one or two diaries ($n = 9$), two respondents confirmed by telephone that they had returned their diaries by post but they were not received and one person gave no reason for their

Table 2. Characteristics of the participants in study 1 and study 2 (percentage unless otherwise stated)

Characteristic	Study 1 (N = 13)	Study 2 (N = 63)
Age (years)		
Mean (SD)	43 (10)	46 (10)
Range	30–66	22–68
Time since diagnosis (years)		
Mean (SD)	12 (10)	11 (8)
Range	1–39	1–31
Sex	77	81
Female	23	19
Male		
Clinical course		
Benign/R. remitting	38	46
Progressive	62	54
Ambulation status Aided		
Unaided	38	48
aided	62	51
Unknown	0	1
Relapse during study		
Yes	15	32
No	85	65
Unknown	0	3

non response. The remaining 6 respondents gave the following reasons for dropping out: feeling too ill to continue ($n = 2$); forgetting to complete the diary ($n = 1$); a serious illness in the family ($n = 1$); feeling better ($n = 1$); diary drew too much attention to MS ($n = 1$).

Those who returned all three diaries were statistically significantly older than those who did not return all three diaries (Mann–Whitney $U = 270$, $p = 0.024$). There were no statistically significant differences in the clinical course, sex or indoor mobility on day of recruitment between responders or nonresponders (data not shown).

On average, respondents fully completed 70 diary days out of a total of 84 (83%), partially completed 10 days (12%) and left four days (5%) fully incomplete. No statistically significant differences were found in any of the missing item summary indicators between those with relapsing remitting/benign MS and those with progressive MS, between those who did or did not use a walking aid or between men and women (data not shown).

Those who experienced a relapse during the study had statistically significantly more missing items and partially completed days, and fewer fully completed days than those who did not experience a relapse (Table 3). However, experiencing a relapse did not result in an increase in respondents missing whole days of the diary.

Fatigue and sensitisation: missing items and symptom reporting

The mean number of missing items showed a statistically significant increase over time, but the mean number of fully complete or incomplete days did not change (Table 4). The mean number of symptoms reported in question 1 did not show any statistically significant decrease over time (Table 4).

Feasibility and acceptability: respondents attitudes

The percentage of respondents who agreed with the attitude statements relating to the feasibility of completing the diary in study 2 are shown in Figure 1. The majority found the questions easy to understand and answer and had got into the habit of filling in the diary everyday, but almost a third also had difficulty remembering to complete the diary everyday. 11% indicated that they had needed help to complete the diary during the study. Almost half of respondents (43%) reported that they had read back over their diaries during the study and of these, 60% found this useful.

Women were statistically significantly more likely to agree that they got into the habit of completing the diary every day ($\chi^2 = 6.2$, $p = 0.013$, $n = 59$). People who had experienced a

Table 3. Missing item summary measures in those that did or did not experience a relapse during the study^a

Missing item summary measure	Median		Mann–Whitney U
	Relapse (N = 20)	No relapse (N = 41)	
Number of missing items (max 2772)	159	27	278*
Number fully incomplete days (max 84)	0	0	375
Number of partially completed days (max 84)	11	5	216**
Number of fully completed days (max 84)	62	78	222**

* $p < 0.05$, ** $p < 0.01$.

^a Two people did not report whether they had a relapse or not, so the total is 31 rather than 63 respondents.

Table 4. Analysis of diary fatigue and sensitisation

Missing item indicator	Diary 1	Diary 2	Diary 3	N	Linear contrast estimate
Mean number of missing items (max 2772)	41.2	53.8	83.7	62	30.1*
Mean number of fully incomplete days (max 84)	0.7	1.4	1.4	62	0.49
Mean number of fully completed days (max 84)	23.8	23.7	22.9	62	-0.63
Mean percentage of symptoms per day (from Q1)	42	42	41	63	-0.009

* $p < 0.05$.

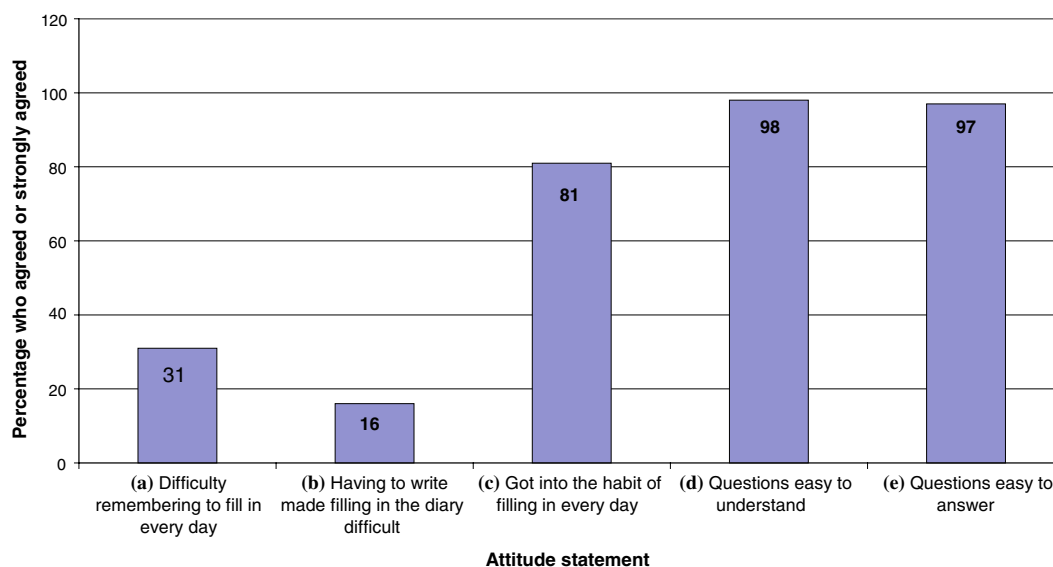


Figure 1. Respondents' view of feasibility of the MSSID.

relapse in the last 3 months were statistically significantly more likely to agree that having to write had made completing the diary difficult ($\chi^2 = 5.1$, $p = 0.024$, $n = 56$). There were no differences in attitudes to the MSSID by clinical course or indoor ambulation status.

Feasibility and acceptability: respondents' experiences of completing the MSSID

Ease of completing the diary

Seventy percent of respondents in study 1 reported finding the diary easy to complete. They reported that the questions were easy to understand and answer and the diary did not take too long to complete each day. Some explained that they became more used to the questions as time went on and got into the habit of completing the diary. The remaining respondents did not find the diary practical to complete because they were too tired or too busy.

Retrospective completion and editing

Some respondents in study 1 reported that they completed the diary every day and did not miss any days, or skip days. However, a number of respondents reported that they forgot to complete the diary during the study and reported that, instead of missing the day completely, they filled it in

the next night. Many qualified this by saying that they would only fill it in if they could remember how they were.

A minority of respondents also discussed the honesty with which they answered the questions. It was evident that, sometimes, the diary asked about symptoms and feelings that respondents found difficult to admit to. Some respondents explained that they answered these as honestly as they could, even if the answer was not one they wanted to see.

However, one respondent reported that he found it very hard to admit to some of the problems he was experiencing and thought he could overcome them, and so did not make a note of them at first. When the problem did not go away, he went back over the diary and filled in the 'correct' answers. He reported feeling a dig to his pride seeing his problems written down in black and white.

Utility: respondents' attitudes to completing the MSSID

The attitudes of respondents in study 2 ($n = 63$) to the utility of the diary are shown in Figure 2. The majority of respondents agreed that the questions in the diary were relevant to them and that the information would be useful for their neurologist and to themselves. Respondents perceived that

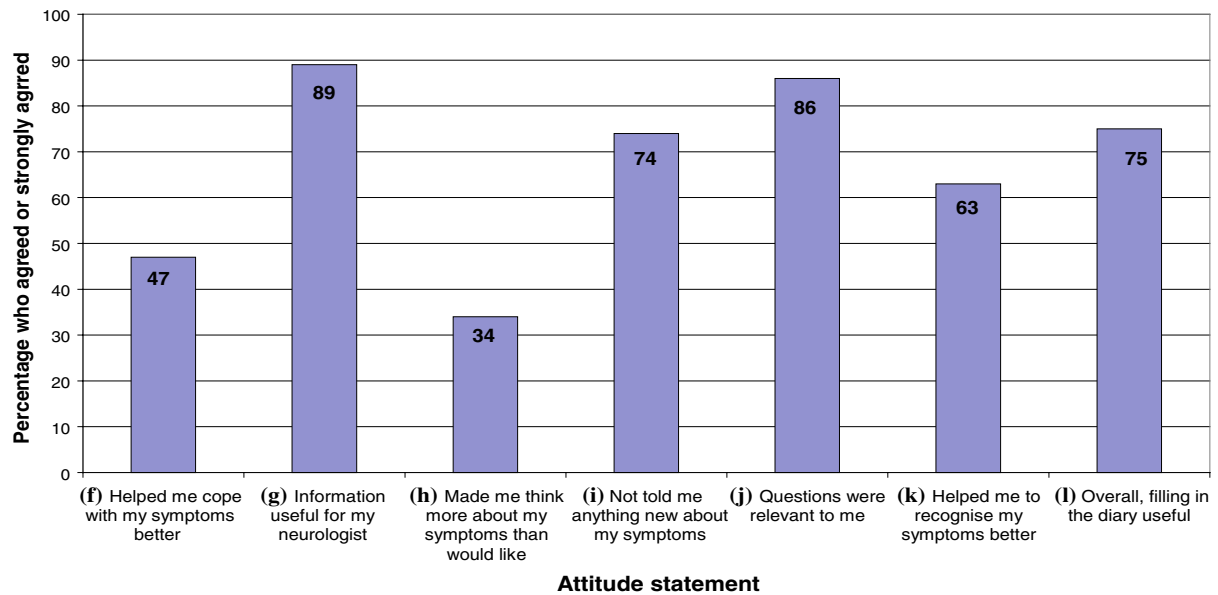


Figure 2. Respondents' view of utility of the MSSID.

completing the diary was more useful in helping them recognise their symptoms than in helping them to cope with their symptoms. Furthermore, three quarters agreed that completing the diary had not told them anything new about their symptoms, and a third agreed that it had made them think more about their symptoms than they would like. There were no differences by sex, clinical course, relapse status or ambulation status in attitudes to the feasibility of completing the MSSID.

Utility: respondents' experiences of completing the MSSID

Increased awareness of MS and symptoms

Almost all respondents in the study 1 interviews and those who provided written comments in study 2 felt that completing the diary had made them more aware of their MS and its symptoms. For some, this had meant a realisation that they had come to accept MS as a normal part of their life and had learned to cope with the symptoms.

For others, it had made them more aware of the reality that they had MS, and that it was not going to go away. It had made it more difficult to deny the existence of their MS and also to realise that, in

the face of no cure, the condition was permanent. For one respondent, it had led her to re-evaluate what she accepted as 'normal'. She indicated that, since completing the diary, she had realised that much of what she 'put up with' was not 'normal'.

Psychological impact of completing the diary

Respondents expressed a range of both positive and negative opinions regarding the psychological impact of completing the diary and the increased awareness that this produced. Some felt that completing the diary had helped them to realise that they did have good days as well as bad days. Others commented that it had been encouraging to see their symptoms improve over time. However, the same respondents also commented that it could also have been quite depressing to have a lot of symptoms or to watch symptoms worsen.

Other respondents commented that the diary had forced them to admit to the presence of new symptoms, which ran contrary to their coping strategy of trying to hide symptoms. This could be distressing as it signalled the possibility that their MS was getting worse. Some respondents felt that completing the diary had been depressing because it had served as a constant reminder of how much MS was affecting their life.

Utility of diary information

Many respondents commented that completing the diary had helped them to understand how their MS was affected by day to day activities. This knowledge had then helped them to manage their lives more effectively through limiting themselves to more manageable tasks, taking rests, or spacing out tasks over a longer period of time. Of the respondents who experienced a relapse during either study 1 or 2, some reported that completing the diary had enabled them to pinpoint when it had begun, and that this information had been very useful for their neurologist.

Some respondents did not find the diary useful. Their method of coping was to look to the future and they felt that it was not helpful to record their symptoms or to dwell on the past. Although the diary may show that symptoms were good on one day, this did not predict what would happen in the future.

Discussion

The potential value of the MSSID in monitoring the impact of MS within clinical practice depends, in part, on whether people with MS find the diary feasible to complete, whether they find the diary personally useful and consequently, on the quality of the resulting data. Few studies have explored the feasibility of health diaries beyond an evaluation of response rates and missing items or considered their value to respondents.

We used quantitative and qualitative methods to gain a more comprehensive evaluation of the potential threats to the validity of the MSSID data and to provide insight into respondents' experiences of completing it. Our findings provide valuable guidance for the use of the MSSID in clinical practice and also raise a number of important issues about the impact of completing health diaries on respondents.

Is the quality of MSSID data good enough for clinical practice?

Uptake of the MSSID was low in contrast to Verbrugge's [8] review where 86–98% of those asked agreed to complete a diary. In this study, the rate of acceptance was difficult to ascertain as

clinicians initially introduced the study to participants and for 86 of the 100 people who did not take part, it is not known whether they were not asked to take part or were asked to take part and refused. Thus, a rate of 43% assumed that all these people were asked but refused. In those who did agree to complete the diary, good completion rates were found, in line with previous diary studies [8–11].

Although some evidence of diary fatigue and attrition bias was found, the quality of diary data was likely to be acceptable for use in clinical practice. As time went on, respondents completed the diary less consistently and completion was also affected by acute events such as relapses. However, in both cases, respondents did not give up completing the diary entirely.

This finding is important because it is at the points before, during and after a relapse when information about symptoms and their impact is of most value to both clinicians and patients within clinical practice [6]. We would hypothesise that those who experienced a relapse focused their energies on completing the items of most relevance to them, and ignored those asking about symptoms and their impact that they did not experience. As few respondents provided precise dates for their relapse, it was difficult to explore whether this hypothesis was supported by our data.

Was there any evidence of bias in MSSID completion?

Some respondents retrospectively completed or edited MSSID data, which has also been found in other diary studies [16, 17]. However, the threats to the quality of the data were limited by the fact that retrospective editing was not widespread and respondents retrospectively completed the MSSID only if they remembered to complete it within one day and could remember how they were feeling. Transforming the MSSID into a timecoded electronic diary would be useful to further minimise retrospective completion.

Our qualitative data showed that retrospective editing occurred because a respondent found it difficult to accept and make public the occurrence of a new symptom. This could be described as social desirability bias, in that the respondent wanted to portray themselves as more healthy than

they actually were [27]. However, this also highlights that completing a questionnaire or diary, even outside an interview situation, is a form of social interaction, and that answering questions about their health is not a neutral activity for the respondent [28]. Respondents actively construct an image of themselves through their answers to questions about their health and may, consciously or unconsciously, manipulate this image through their answers [29].

Our findings suggest that this image gains a more 'permanent' status where a diary is concerned as responses are written down in black and white and can be reviewed at a later date. Indeed, a number of our respondents in this study connected the emotional impact of completing the diary to the fact that their symptoms were more difficult to deny now that they were written down.

Our findings also suggest that completing a diary may have led respondents to re-evaluate what they accepted as 'normal' in relation to their health. This process of re-evaluation may be similar to the phenomenon of response shift [30]. It could be hypothesised that the process of writing a diary and the consequent increase in awareness is a possible catalyst to one or more elements of response shift. However, it was beyond the scope of the study to confirm this and examine whether this had influenced respondent's ratings in the MSSID.

In summary, completing the MSSID raised respondents' awareness of their MS or led them to face up to symptoms they may have preferred to deny. This gave rise to a number of different emotional reactions that may have had an influence on data quality. While these reactions are likely to be more prominent in diary completion, it is possible that completion of single point HRQoL measures may give rise to similar responses, and are thus worthy of further study to explore their impact on HRQoL data.

Did respondents find the diary feasible and useful to complete?

An assumption of this study is that respondents are more likely to complete a diary if they find it feasible and personally useful to complete. The MSSID was more acceptable to women and they were also more likely to get into the habit of completing it. Overall, respondents' attitudes to

the feasibility of the diary were positive. However, some respondents did find the diary over burdensome to complete and felt that it focused their attention too much on their MS.

This presents ethical issues for the use of the MSSID in clinical practice. The potential positive and negative impact of the completing the MSSID needs to be fully explained to respondents and a formal mechanism of stopping completion needs to be provided.

In contrast, some respondents used the MSSID as a tool to monitor and understand their own symptoms, supporting findings from previous diary studies [20–23]. For these respondents, the MSSID became more than just a data collection method for the researcher. The psychological impact of the diary and degree to which respondents found the diary useful appeared to be related to the ways in which respondents coped with their MS.

This suggests that within clinical practice, the MSSID will not be appropriate to everyone, and its value to both patients and clinicians will depend on the degree to which the diary is likely to augment or militate against the coping strategies that are already used by the respondents. A full exploration of the interaction between completion of the diary and respondents coping strategies was beyond the scope of this study, but would benefit from further research.

Limitations of the study

This study had a number of weaknesses that need to be taken into account when considering its results. The sample size was relatively small and was drawn from outpatient clinics who may not be representative of the general MS population [31]. There were almost five times as many women as men in the sample, which is a higher ratio than that usually found in population studies [32, 33]. Women may have been more likely to take part in the study because they had more positive attitudes towards completing a diary, and may have biased the results towards a more positive evaluation of the MSSID.

The interviews were conducted by the MSSID developer and respondents may have been reluctant to give negative feedback. More accurate data may have been obtained had an independent

interviewer been used. Furthermore, only 35% of respondents answered the open ended questions at the end of study 2, and those with negative experiences may have been less inclined to reply. This low response rate may also be related to the difficulty some respondents may have had in providing a written response as compared to ticking a box to answer the attitude statements.

Respondents completed the MSSID for only 3 months, which is shorter than the time interval between successive neurologist appointments in clinical practice. However, other diary studies have shown that drop outs were mostly likely to occur at the start of the study and completion rates tend to remain constant even over long periods of time [8, 13]. Relapses were measured using self report and not confirmed by a neurologist. It is possible that some of the relapses reported in this study would not meet clinical definitions of a relapse [34] and that some relapses may have gone unreported.

Conclusions and future research

This initial assessment of the feasibility and utility of the MSSID has provided promising results. It has also raised a number of areas for future research. The problem of retrospective completion could be minimised or at least monitored by providing an electronic form of the MSSID [17]. Application of item response theory and the integration of computer adaptive testing to an electronic form of the MSSID would enable respondents to focus on symptoms and their impact that are of most relevance to them, and possibly reduce the number of missing items [35]. Further work is also required to identify who might find the diary most useful as a tool to monitor symptoms through more systematic measurement of the coping strategies used by respondents.

There are many constraints on the use of HRQoL measures in clinical practice and there is often a gap between the ideal conditions for their use and the reality of clinical practice [36]. This study focused only on patients' perceptions of the MSSID and further work is needed explore clinicians' perceptions of its utility. This includes determining the most appropriate way of summarising and presenting MSSID data to clinicians

and exploring whether its use enables patients to communicate more effectively to clinicians about their symptoms and their impact.

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Address for correspondence: Joanne Greenhalgh, Health Care Practice R&D Unit, Allerton Building, University of Salford, Frederick Road, Salford M66PU, UK
Phone: +44-161-295-0455; Fax: +44-161-295-2825
E-mail: j.greenhalgh@salford.ac.uk