

The Development, Validity, and Responsiveness of a Patient-Centred Outcome Measurement Tool for Evaluating Integrative Medicine Interventions

Fernando Cabo, MSc,* Neil Browne, MSc

Complementary Therapies Department, Barts Health NHS Trust, Margaret Centre, Whipps Cross Hospital, London, United Kingdom

<https://doi.org/10.3822/ijtmb.v16i3.859>

Background: The paper sets out the development, validity, and responsiveness of the Integrative Medicine Treatment Evaluation Form (IMTEF), which has been designed to measure the effects of complementary and integrative therapy (CIT) interventions in cancer and palliative care (PC) patients in a National Health Service (NHS) hospital setting. Treatment evaluation is essential for ensuring safety and quality of services, for meeting NHS governance requirements. It also helps to add to the evidence base for complementary and integrative therapies through collecting data about treatments.

Methods: A number of different Patient Reported Outcome Measures (PROMs) tools were reviewed in order to design the IMTEF, which details questions that captures both quantitative and qualitative data. The IMTEF was reviewed by patients and a range of health care practitioners.

Results: IMTEF's validity is supported by feedback from health care practitioners and patients, by its ability to detect different degrees of change in relation to change scores, and by its correlations with Visual Analog Scale (VAS) scores.

Conclusion: The IMTEF can be used to assess the effects of therapeutic bodywork and CITs when many of the patients do not have the capacity or the time to answer many questions, and when therapists do not know in advance the number of treatments that patients will be able to receive. Because of the way it is structured, it can also assess the effects after a number of sessions.

KEYWORDS: integrated oncology; complementary therapies; therapeutic bodywork; assessment; validation

INTRODUCTION

It is generally assumed that evaluating the effects of Complementary and Integrative Therapies (CITs) is essential for the development of a sound evidence base to gauge whether the interventions are beneficial, to improve the quality of the delivery of CITs, and to improve patient satisfaction.⁽¹⁻³⁾ Indeed, evaluating treatments is seen as essential by the National Institute for Clinical Effectiveness.⁽⁴⁾ There is growing evidence that CITs interventions, such as massage, reflexology or other types of therapeutic bodywork, can help with symptom management, increased wellbeing, and quality of life.^(2,3,5,6) It has been hypothesized that therapeutic bodywork stimulates the pressure mechanoreceptors found in human skin, which enhances vagal activity and reduces cortisol levels, which means that the body responds faster to stress and relaxes more quickly.⁽⁷⁾ There is also a general consensus on the relevance of patient-reported outcomes in clinical research.⁽⁸⁾ Subjective questionnaires allow patients to be involved in assessing the outcome of treatments, and make research findings more relevant to patients.⁽⁹⁾ CITs are used to support people through their treatment and to improve their quality of life.^(4,10)

This paper presents the development and validation of the final version of the Integrative Medicine Treatment Evaluation Form (IMTEF) (see Appendix A), a four-item CITs measuring tool developed by the Bart's Health CITs team. Although it has been specifically designed to be used in a cancer and PC setting, as with other forms, it can probably be used in any type

of setting with healthy or ill patients. This assessment tool has undergone several changes before reaching its current form. These changes have been informed by patients' comments, ideas from complementary therapists and nursing, medical and allied health practitioners in the wards, and the aforementioned assessment tools. The IMTEF may be used free of charge in other settings; however, Bart's Health NHS Trust should be acknowledged and this research paper should be cited.

METHODS

Setting and Objectives

The Barts Health Complementary Therapies Service was established in 2005 at Whipps Cross Hospital in London, with the aim of providing CITs to cancer and PC patients.⁽¹¹⁾ The service started by providing CITs mostly to outpatients who travelled to the hospital for a course of treatments. A simplified version of the Distress Thermometer (DT without the problem list) for pre- and post-treatment scores was used for the hospitalized patients who were treated occasionally.⁽¹²⁾

At the request of the Trust, the service was extended to St Bartholomew's Hospital (Barts), first in 2016 for outpatients who have an appointment to receive chemotherapy, and later in 2017 to hospitalized patients in the cancer wards. During the time the data were collected, the service was offered two days per week with CITs being offered on Mondays for outpatients and on Mondays and Thursdays for hospitalized patients. The service operated and still operates on an ad hoc basis, with patients self-referring for CITs. This means that it is never known if a particular person is going to receive only one session or more than one, since they may have been discharged, or have an outpatient appointment for a day in which the service is not running. The CITs team felt that most of the PROMs analyzed were not appropriate for situations in which the patient might receive a single CIT treatment since they had been designed to measure the effects of a number of sessions. Those that could be used to measure the effects of only one intervention were deemed to be either condition specific or too generic for the type of patient and feedback the

team wished to collect. The team wanted to have a more individualized PROM (iPROM).⁽¹³⁾

The CITs team consisted of the lead complementary therapist who practices massage, aromatherapy, reflexology, and reiki, as well as one massage therapist, one reflexologist, two shiatsu therapists, one biodynamic massage therapist, and two reiki therapists. The CITs team decided to create a treatment feedback form on the basis that the number of treatments is not known in advance, that the form should reflect the effects of the treatments on patients' concerns, and that it should be simple and quick to complete. The CITs on offer at the time of writing are: aromatherapy, massage, biodynamic massage, reflexology, reiki, and shiatsu.

Data during the pilot phase were collected as part of the service evaluation of the CITs offered at St. Bartholomew's Hospital.

Review of CITs PROMs Literature

PROMs instruments should be user-friendly to patients and health care teams, as well as be easy to interpret and relevant to the effects of the intervention.⁽¹⁴⁾ Although there is a plethora of PROMs for many conditions, it is recognized by Complementary and Integrative Medicine (CIM) researchers that the present forms cannot always be used adequately to present the results of treatments.⁽¹⁾

The potential instruments for evaluating the effects of single CIT treatments were identified and examined. Relevant tools to assess CITs among cancer and PC patients, even those that were deemed to be more appropriate for measuring the effects of several sessions, were presented for discussion among the team since the team felt they could provide interesting clues for the development of the proposed form.

The tools that were identified and examined were:

1. The Short-Form 36-Item Health Survey which has been used with cancer survivors.⁽¹⁵⁾
2. The Arizona Integrative Outcomes Scale (AIOS), which had the advantage of being a single-item, self-rating tool, akin to what the team had in mind, and is CIT-specific.⁽¹⁶⁾
3. Measure Yourself Concerns and Well-being MYCaW is cancer- and palliative

- care-specific and developed to measure the effects of CIT interventions.⁽¹⁷⁾
4. The simplified DT had been used by the team, but other versions of the DT with the problems list, were also examined. The DT has widely been used with CITs in cancer settings.^(18,19)
 5. The revised Edmonton Symptom Assessment System (ESAS-r). The Edmonton Symptom Assessment Scale (ESAS) was developed to measure a series of symptoms in PC,⁽²⁰⁾ and has been used in CIT research.⁽²¹⁻²³⁾
 6. The Memorial Pain Assessment Card (MPAC) which although only used for pain assessment has proven to be useful when assessing CIT treatments for hospitalized cancer patients.^(24,25) The MPAC and the AIOS are the simplest forms using a Visual Analog Scale (VAS).

Subjects

A total of 13 health care practitioners working in the cancer wards were given the IMTEF form to study and were asked to answer a reflective question on the form. The answers have a numerical value to identify more easily the results (Appendix B). Out of these 13 health care providers, five were complementary therapists who used the forms with the patients regularly.

Eighty-eight hospitalized patients, with different types of cancer, were asked to evaluate the functionality and understandability of the IMTEF form, after they had received their treatment and had completed the form. Inclusion criteria for the study were (1) being hospitalized at St Bartholomew's Hospital in London at the moment of CIT treatment, (2) a cancer diagnosis, (3) agree to receive a CIT treatment, (4) ability to give informed consent, and (5) ability to complete the questionnaire.

Development and Design Criteria

CITs by their very nature are individualized treatments,^(26,27) so it is appropriate to design an evaluation form with outcomes research in mind. Individualized outcome evaluation forms are particularly suited to the provision of holistic care.⁽²⁸⁾

As with other forms, the Barts Health CIT team is designed to collect qualitative and quantitative data in the simplest way possible. The first version of IMTEF included one open question of how the treatment had helped the patient and one quantitative

question, in which the patient had to score one concern before and after treatment.

The Questions

After piloting the first version and hearing comments from patients and health workers in the ward and in the Chemotherapy Unit, it was decided to alter the form by adding two questions and changing the scales to make them easier to interpret. A new question on mood was added since it was felt that sometimes patients may not feel measurable improvements for a particular concern, but the treatment has made them feel better nonetheless. It was decided that the assessment of mood is an important indicator for the evaluation of short-term intervention effects.^(29,30)

Another question was added to ask patients how much relief they got for a particular problem or concern. This question is not intended to be asked for every type of concern. The team believes that this question need not be asked when patients only want help with relaxation for example, but it is important to ask when they need help with concerns for which relief is more immediately measurable such as pain, digestive disorders, nausea or shortness of breath. A question about relief has been included in other questionnaires or studies on pain,^(31,32) digestive disorders,⁽³³⁾ headaches,⁽³⁴⁾ restless legs syndrome,⁽³⁵⁾ and general symptom relief for enlarged prostate.⁽³⁶⁾

The Scales

The CIT team decided to follow patients' comments about the quantitative/scoring questions in the form and have a standard 0 to 10 numerical rating scale (NRS) for the concern for which a patient may want help. Most mood scales ask a person to rate one's mood from 0 to 10, with many having the middle of the scale, a score of 5, described as 'not happy, not sad' or 'so-so'.^(37,38) The CITs team however, decided that a scale from -5 to 5, with zero as neutral, would be more accurate since it includes negative integers and, therefore, it is clearer whether one's mood is positive or negative.⁽³⁹⁾ It was decided to assess relief using a 4-point categorical scale (no relief, slightly relieved, mostly relieved, complete relief). It was felt by the team that having different scales for each quantitative item would reduce ambiguity.

Other Data Captured by IMTEF

Other studies have identified certain shortcomings of CITs assessment forms when trying to convey information that may be relevant to research studies, such as frequency and duration of CIT treatments.⁽⁴⁰⁻⁴²⁾ Therefore, IMTEF includes NHS number (or similar) to identify the patient and to easily compute number of sessions received. It also includes approximate duration of treatment, time in which treatment took place and, to take into account possible cluster effects,⁽⁴³⁻⁴⁵⁾ location of treatment and name of therapist. It also includes information on who asks the questions. It is felt that when an enumerator collects the data, response bias is reduced, although not completely eliminated.⁽⁴⁶⁾

The form can also record unsolicited comments that patients sometimes make which, in the opinion of the team, add more qualitative information on their perception of the treatments.

Finally, the form includes codes for instances when the form cannot be completed, such as when the treatment had to be stopped because the patient needed to go for a medical procedure. In this way, data can be collected to specify percentage of treatments assessed and reasons for incomplete assessments.

RESULTS

Face and Content Validity

The form was tested for functionality, understandability, and content validity during a pilot period of ten months in which 88 patients, one doctor, four allied health care practitioners, three nurses, and five complementary therapists were asked for their opinions about the form. The patients were asked to complete the form before and after treatment, and then asked if they understood the questions and the scales easily and whether they thought the form measured what it intended to measure—i.e., the effect of the CIT treatment for the

concern they had expressed and their change of mood and relief for their particular concern, if appropriate. Since the IMTEF is comprised of only four items, the feedback on the form was sought for the whole form rather than for individual questions. Nonetheless, all those asked could and did give feedback on the form as a whole and on specific aspects of it.

The health care practitioners (i.e., the doctors, nurses, allied healthcare practitioners, and the complementary therapists) were shown the IMTEF and asked the question: ‘How suitable is the IMTEF feedback form for obtaining feedback from patients on the effects of a complementary therapy treatment for a particular patient-identified problem?’ There were four options: ‘The form is very suitable for that purpose’, ‘The form is adequate’, ‘The form is inadequate’, and ‘The form is unsuitable for that purpose’. In addition, there was a section to make further comments (Appendix B). As shown in Table 1, the health care practitioners agreed among them that the IMTEF form was suitable for the stated purposes and the setting in which the services were delivered. A number was assigned to each answer to qualitatively measure the responses. A total score of 49 out of a maximum of 52 (94%) resulted from the replies, which represented high level of agreement among the health care practitioners on the appropriateness of the form.^(47,48) Table 1 shows the results.

The Patients

Eighty-eight randomly selected patients with different types of cancer and a mean age of 56 years were asked to give feedback on the form. The patients had to fill in the form for the treatment and were asked at the end whether they had found the form and the scales easy to understand and whether they thought the form was appropriate to measure the effects of the integrative therapies. Ten forms were discarded by the research team because they had been filled in incorrectly by the therapists. Four of the discarded forms had the concern scored between two

TABLE 1. Health Care Practitioners Replies on the Suitability of the IMTEF

	Very Suitable (+4)	Adequate (+3)	Inadequate (+2)	Unsuitable (+1)	Maximum = 52 Minimum = 13	Total 49
N = 13	10	3	0	0		

numbers, three had written more than one concern, two lacked any score for the concern, and one did not have a clear concern. Guidance notes for completing the IMTEF form have been drafted and appear in Appendix C.

Out of the remaining 78 patients, 66 (84.6%) gave clear positive feedback on ease of use and understanding and appropriateness of form for evaluation of the CIT treatment. Of the remaining 12, seven (9%) patients said they understood the questions, but they replied either that it was difficult to put a number on how they felt, or that they did not feel like replying when they felt so relaxed. Three patients (3.8%) said they found the scales confusing and two (2.6%) slightly confusing but overall good. Eighty-seven percent (n=68) of patients felt the form was apt to measure the effects of therapies (see Table 2).

In spite of the fact that a minority found the scales confusing or slightly confusing (6.4% of respondents), it is assumed that in general Numerical Rating Scales, as the ones used for mood and concerns in IMTEF, and categorical scales, as the one used for relief in IMTEF, are easier to use and to understand both for the researcher and the respondent.⁽⁴⁹⁾

Generally speaking, patients prefer the NRS to score the severity of their symptoms over other measures including the VAS due to ease of understanding and ease of completion, although some of them prefer the VAS because they feel their symptoms do not fall exactly on one particular integer.⁽⁵⁰⁻⁵²⁾

Concurrent Validity and Reliability

To establish criterion (concurrent) validity, the research team searched for another instrument with which to compare the IMTEF.⁽⁴⁷⁾ The team could not identify an outcomes research questionnaire appropriate for measuring the effects of only one CIT treatment with which the IMTEF could be easily compared. In order to establish concurrent validity patients were asked to

score the same questions regarding their concern and mood pre- and post-treatment, plus relief (if appropriate) with Visual Analog Scales (VAS) almost at the same time as when asked to score in the IMTEF scales. The validity and responsiveness of independently administered VAS and NRS, as well as VAS and Likert-type scales, have been determined in several studies^(49,53-55) and the VAS has been extensively used to measure the effects of one treatment of CIT.⁽⁵⁶⁻⁵⁸⁾

The VAS scales for concern and relief were simple, with worst possible and best possible marked at the endpoints, while the one for mood also had a middle point marked which corresponds to zero or neutral mood (i.e., positive mood to the right of the middle mark, negative mood to the left) in the IMTEF scale.

Thirty-eight patients were asked to score their concerns, mood, and relief (if appropriate) on the IMTEF and on the VAS. Most of the concerns were for pain or muscular tightness (19 patients), with two cases of headaches, two of anxiety, and three for lack of energy. Twelve patients only wanted to feel more relaxed so they were not asked how much relief they had experienced; 26 patients answered the relief question.

The Pearson’s correlation coefficient was used to describe the relationship between the IMTEF and the VAS scales at baseline and post-treatment for concern and mood (see Table 3). In all cases, there was a strong correlation between the numerical scales and the VAS (see Figures 1 to 4). As seen in Table 3, the Pearson’s correlation coefficient, in all cases, was very near one, giving a very highly positive linear relationship between the variables, meaning that the perception of concerns before and after treatments was equally valid on the IMTEF’s NRS and the VAS.

For the relief question, each of the obtained categories was compared to the mean of the values obtained in the VAS form (see Table 4). Table 4 shows that the results from the IMTEF are quite accurately comparable to the replies given.

TABLE 2.

	<i>Easy to understand</i>	<i>Confusing</i>	<i>Slightly confusing</i>	<i>Form is apt to measure effects of therapies</i>	<i>Did not feel like replying</i>
N = 78	66	3	2	68	7
Percentage	84.6%	3.8%	2.6%	87%	9%

TABLE 3.

	Numerical Scale Mean (SD) Median	VAS (10 cm) Mean (SD)	Pearson's Correlation Coefficient <i>r</i>	Coefficient of Determination <i>r</i> ²	<i>P</i> value
Pre-tx Concern n=38	6.40 (2.16) 6	6.31 (2.35)	0.99	0.97	<i>p</i> <.0001
Post-tx concern n=38	1.82 (1.50) 1	1.68 (1.44)	0.97	0.95	<i>p</i> <.0001
Pre-tx Mood n=38	0.37 (2.34) 0	0.36 ^a (2.40)	0.99	0.99	<i>p</i> <.0001
Post-tx Mood n=38	3.21 (1.42) 3	3.13 ^a (1.48)	0.98	0.96	<i>p</i> <.0001

^aVAS cm measured from the midpoint which equals 0 on the -5 to 5 scale.

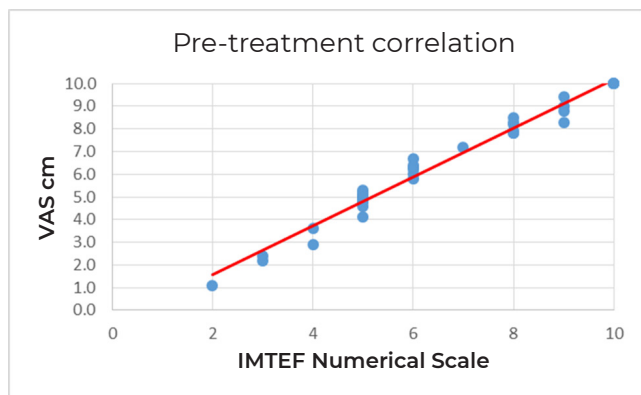


FIGURE 1. Pre-treatment correlation

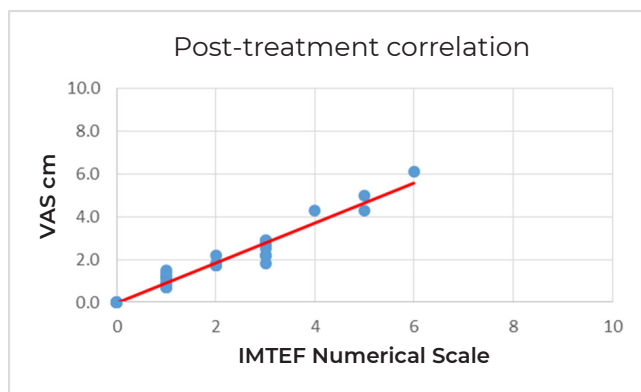


FIGURE 2. Post-treatment correlation

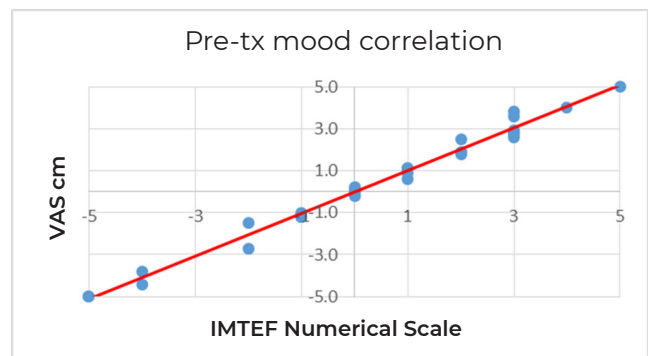


FIGURE 3. Pre-tx mood correlation

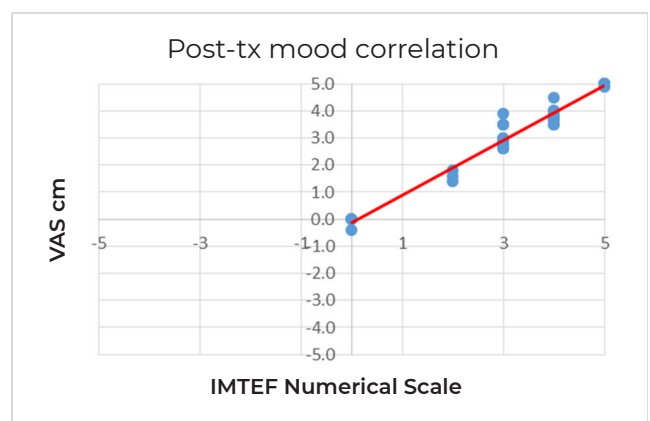


FIGURE 4. Post-tx mood correlation

Responsiveness

To analyze the sensitivity to change of the IMTEF, the data of all patients have been combined, from those who gave

feedback about the form and those who filled in the form and the VAS.

The responsiveness indices, Standardized Response Mean (SRM) and the Effect Size (ES), were calculated for the change

TABLE 4.

Relief	VAS (10 cm) Mean (SD)
Completely n=5	9.84 (0.36)
Mostly n=18	7.46 (0.99)
Slightly n=3	2.60 (1.13)
No relief n=0	N/A

scores data for the concern and the mood as a group. The IMTEF mood and concern scores were highly responsive to change (see Table 5).

Although the mood score was not as sensitive to change as the concern score, the IMTEF showed higher responsiveness indices compared to other forms used with cancer and palliative care patients, such as the FACIT-SpEx.⁽⁵⁹⁾

DISCUSSION

This study describes the successful development and validation of the IMTEF. This new outcome measure has been produced to measure the impact of therapeutic bodywork and CITs on the concerns that cancer patients present while hospitalized, even if some of these concerns predate their hospitalization. This form, however, can be used in many other settings. The field of bodywork and CITs requires a strong evidence base that incorporates health outcome measurement from the patient perspective. Appropriately constructed and validated instruments that take into account the circumstances in which the therapists have to work are

required to fully capture and quantify the patients' viewpoint.

The authors believe this form can be used in many different settings, and it is useful for the collection of data by massage therapists, osteopaths, reflexologists, and any other therapists in the field of CITs and therapeutic bodywork, because of the inclusion of certain advantageous features. It names the type of therapy being administered, which would allow to present evidence for one therapy in particular, or for several together, if it is preferred to use as evidence for a particular service as is our case. It has patient identification and date of treatment, giving the opportunity to see the difference between more frequent sessions and/or higher number of sessions. The simplicity of the form means that any therapeutic bodywork school can make use of the form to initiate students in the field of research. IMTEF is a form that does not require either a long time or too much thinking on the part of the patient nor the therapist, making it appropriate and simple to use for case reports, where it would be particularly useful.

Some researchers in the field of bodywork and CITs are turning to the use of more objective measurements to the relaxation response, such as salivary cortisol.⁽⁶⁰⁻⁶²⁾

Cortisol normal ranges vary from person to person and change throughout the day. The fact that IMTEF comprises time and duration of treatment can help differentiate in these cases between actual effect of treatment and the natural cortisol circadian rhythm.⁽⁶³⁾

The service in which IMTEF was designed delivers bodywork and CITs to a variety of patients, including those who are acutely unwell, symptomatic of their conditions or experiencing the side effects of medication/allopathic treatments. The priority

TABLE 5.

IMTEF	Mean (SD) Pre-tx	Mean (SD) Post-tx	Mean Change (SD) (95% CI)	P value	SRM	ES (Cohen's d)
Concern n=112	6.20 (2.19)	2.36 (1.88)	3.84 (1.91) (3.48-4.20)	p<.0001	2.01	1.88
Mood n=112	0.69 (2.50)	3.13 (1.57)	2.45 (2.14) (2.05-2.85)	p<.0001	1.14	1.17

in designing a PROMs form was to avoid any unnecessary burden on patients with long lists or time-consuming questions, so it was decided to keep the form as short as possible with very few items. The CITs team also felt that it is important to work and collect data on any concerns patients feel are relevant to them at the moment when they receive CIT treatments, something which is not possible with a predetermined list of items; hence, the team decided to include only self-reported concerns/outcomes items.⁽⁶⁴⁾ This puts the patient and their experience at the centre of the treatment and of the measuring of its outcome.

The team believes that, to measure accurately the results of their interventions, a patient's perceptions and desires must be understood in their context, and that CITs can help in a wide range of cases, including when patients are only looking for some relaxation in a highly stressful environment.

The authors believe it is reasonable to state the results of the use of the IMTEF as shown in this study, and the replies given by the majority of patients demonstrate the validity, reliability, and practical usefulness of the form without burdening the patients.

LIMITATIONS

The IMTEF form may have some limitations that need to be considered. The possibility of response bias in self-reported questions is well-known. Patients may feel they are

supposed to have benefited more than what they actually have. This might be accentuated when patients answer the questions in the presence of the therapist who has delivered the treatment and the patients want to make them feel good about themselves. One way to attenuate this possibility is to have a different person collect the results of the questions. This form needs to be tested in other settings and with different patient populations in order to show its validity in those cases.

CONCLUSION

This paper reports the validity and responsiveness of a new evaluation tool, the IMTEF, to assess the effects of therapeutic bodywork and CITs in integrative cancer care, although it can probably be used for a

target population with other health conditions seeking these types of therapies for the relief of their symptoms.

The IMTEF was developed in line with the holistic needs assessment of cancer patients that highlights the person's concerns or problems and allows the complementary therapists to devise a personalized course of treatment.⁽⁶⁵⁾ It also helps the CIT team to work more efficiently, and can be used for outpatients and hospitalized patients in different health care models in integrative cancer care.

IMTEF's validity is supported by feedback from health care practitioners and patients, by its ability to detect different degrees of change in relation to change scores, and by its correlations with VAS scores.

We also believe the IMTEF is filling a gap in the evaluation tools that can be used to assess the effects of bodywork and CITs when many of the patients do not have the capacity or the time to answer many questions and when therapists do not know in advance the number of treatments that patients will be able to receive. This does not mean it can only be used in these circumstances. It can also assess the effects after a number of sessions, even if the number of these has been pre-arranged, because of the way it is structured and because there is a patient identification number.

ACKNOWLEDGMENTS

The authors wish to give thanks to all the volunteer complementary and integrative therapists at Bart's Hospital who have made the service and the collection of data possible.

CONFLICT OF INTEREST NOTIFICATION

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. No funding was received for conducting this study.

COPYRIGHT

Published under the [Creative Commons Attribution-NonCommercial-NoDerivs 3.0 License](https://creativecommons.org/licenses/by-nc-nd/3.0/).

REFERENCES

1. Verhoef MJ, Vanderheyden LC, Dryden T, Malloy D, Ware MA. Evaluating complementary and alternative medicine interventions: in search of appropriate patient-centered outcome measures. *BMC Complement Altern Med*. 2006;6:6–38. doi:10.1186/1472-6882-6-38
2. Richardson J, Pilkington K. Evaluating complementary therapies. In: Barraclough J, editor. *Enhancing Cancer Care: Complement Therapy and Support*, 1st ed. New York: Oxford University Press; 2007. pp. 11–28. doi:10.1093/acprof:oso/9780199297559.001.0001
3. Kelemen A, Anderson E, Jordan K, Cates LC, Shipp G, Groninger H. “I Didn’t Know Massages Could Do That.” A qualitative analysis of the perception of hospitalized patients receiving massage therapy from specially trained massage therapists. *Complement Ther Med*. 2020;52:102509. doi:10.1016/j.ctim.2020.102509
4. National Institute for Clinical Excellence (NICE). *Improving Supportive and Palliative Care for Adults with Cancer: The Manual*. London: 2004. <https://www.nice.org.uk/guidance/csg4/resources/improving-supportive-and-palliative-care-for-adults-with-cancer-pdf-773375005>
5. Ferguson PE, Persinger D, Steele M. Resolving dilemmas through bodywork. *Int J Ther Massage Bodywk*. 2010;3(1):41–47. doi:10.3822/ijtm.v3i1.74
6. Porcino AJ. Advancing the therapeutic massage research agenda(s). *Int J Ther Massage Bodywk*. 2013;6(3):1–2. doi:10.3822/ijtm.v6i3.229
7. Field T. Massage therapy research review. *Complement Ther Clin Pract*. 2016;24:19–31. doi:10.1016/j.ctcp.2016.04.005
8. Black N. Patient reported outcome measures could help transform healthcare. *BMJ*. 2013;346. doi:10.1136/bmj.f167.
9. Paterson C. Seeking the patient’s perspective: a qualitative assessment of EuroQol, COOP-WONCA charts and MYMOP. *Qual Life Res*. 2004;13:871–881. doi:10.1023/B:QURE.0000025586.51955.78
10. Maindet C, Burnod A, Minello C, George B, Allano G, Lemaire A. Strategies of complementary and integrative therapies in cancer-related pain—attaining exhaustive cancer pain management. *Support Care Cancer*. 2019;27:3119–3132. doi:10.1007/s00520-019-04829-7
11. Briscoe J, Browne N. Effects of complementary therapies in cancer care. *Nurs Times*. 2013;109(41):16–22.
12. Snowden A, White CA, Christie Z, Murray E, McGowan C, Scott R. The clinical utility of the distress thermometer: a review. *Br J Nurs*. 2011;20(4):220–227. doi:10.12968/bjon.2011.20.4.220
13. Benson T. Person-specific outcome measure (PSO) for use in primary and community care. *BMJ Open Qual*. 2021;10(2):e001379. doi:10.1136/bmjopen-2021-001379
14. Bodger K, Ormerod C, Shackcloth D, Harrison M. Development and validation of a rapid, generic measure of disease control from the patient’s perspective: the IBD-control questionnaire. *Gut*. 2014;63(7):1092–1102. doi:10.1136/gutjnl-2013-305600
15. Helgesson Ö, Lissner L, Månsson J, Bengtsson C. Quality of life in cancer survivors as observed in a population study of Swedish women. *Scand J Prim Health Care*. 2007;25(4):220–225. doi:10.1080/02813430701669535
16. Bell IR, Cunningham V, Caspi O, Meek P, Ferro L. Development and validation of a new global well-being outcomes rating scale for integrative medicine research. *BMC Complement Altern Med*. 2004;4(1):1. doi:10.1186/1472-6882-4-1
17. Jolliffe R, Collaco N, Seers H, Farrell C, Sawkins MJ, Polley MJ. Development of Measure Yourself Concerns and Wellbeing for informal caregivers of people with cancer—a multicentred study. *Support Care Cancer*. 2019;27:1901–1909. doi:10.1007/s00520-018-4422-8
18. Grassi L, Johansen C, Annunziata MA, Capovilla E, Costantini A, Gritti P, et al. Screening for distress in cancer patients: a multicenter, nationwide study in Italy. *Cancer*. 2013;119(9):1714–1721. doi:10.1002/cncr.27902
19. Keir ST, Saling JR. Pilot study of the impact of massage therapy on sources and levels of distress in brain tumour patients. *BMJ Support Palliat Care*. 2012;2(4):363–366. doi:10.1136/bmjspcare-2012-000224
20. Chang VT, Hwang SS, Feuerman M. Validation of the Edmonton symptom assessment scale. *Cancer*. 2000;88(9):2164–2171. doi:10.1002/(SICI)1097-0142(20000501)
21. Tsang KL, Carlson LE, Olson K. Pilot crossover trial of Reiki versus rest for treating cancer-related fatigue. *Integr Cancer Ther*. 2007;6(1):25–35. doi:10.1177/1534735406298986
22. Lim JT, Wong ET, Aung SK. Is there a role for acupuncture in the symptom management of patients receiving palliative care for cancer? A pilot study of 20 patients comparing acupuncture with nurse-led supportive care. *Acupunct Med*. 2011;29(3):173–179. doi:10.1136/aim.2011.004044
23. Nainis N, Paice JA, Ratner J, Wirth JH, Lai J, Shott S. Relieving symptoms in cancer: innovative use of art therapy. *J Pain Symptom Manag*. 2006;31(2):162–169. doi:10.1016/j.jpainsymman.2005.07.006
24. Rao A, Cohen HJ. Symptom management in the elderly cancer patient: fatigue, pain, and depression. *J Natl Cancer Inst Monogr*. 2004;2004(32):150–157. doi:10.1093/jncimonographs/lgh031
25. López-Sendín N, Alburquerque-Sendín F, Cleland JA, Fernández-de-las-Peñas C. Effects of physical therapy on pain and mood in patients with terminal cancer: a pilot randomized clinical trial. *J Altern Complement Med*. 2012;18(5):480–486. doi:10.1089/acm.2011.0277

26. Joske DJ, Rao A, Kristjanson L. Critical review of complementary therapies in haemato-oncology. *Intern Med J*. 2006;36(9):579–586. doi:10.1111/j.1445-5994.2006.01152.x
27. Langmead L, Rampton DS. Complementary and alternative therapies for inflammatory bowel disease [review article]. *Aliment Pharm Ther*. 2006;23(3):341–349. doi:10.1111/j.1365-2036.2006.02761.x
28. Paterson C. Quality of life measures. *Br J Gen Pract*. 2010;60(570):53. doi:10.3399/bjgp10X482121
29. Lutgendorf SK, Anderson B, Ullrich P, Johnsen EL, Buller RE, Sood AK, et al. Quality of life and mood in women with gynecologic cancer: a one year prospective study. *Cancer*. 2002;94(1):131–140. doi:10.1002/cncr.10155
30. Specia M, Carlson LE, Goodey E, Angen M. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosom Med*. 2000;62(5):613–622. doi:10.1097/00006842-200009000-00004
31. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore*. 1994;23(2):129–138. doi:10.1016/0029-7844(94)00457-0
32. Fishman B, Pasternak S, Wallenstein SL, Houde RW, Holland JC, Foley KM. The Memorial Pain Assessment Card. A valid instrument for the evaluation of cancer pain. *Cancer*. 1987;60(5): 1151–1158. doi:10.1002/1097-0142(19870901)
33. Carlsson R, Dent J, Bolling-Sternevald E, Johnsson F, Junghard O, Lauritsen K, et al. The usefulness of a structured questionnaire in the assessment of symptomatic gastroesophageal reflux disease. *Scand J Gastroenterol*. 1998;33(10):1023–1029. doi:10.1080/003655298750026697
34. Fogan L. Treatment of cluster headache: a double-blind comparison of oxygen vs. air inhalation. *Arch Neurol*. 1985;42(4):362–363. doi:10.1001/archneur.1985.04060040072015
35. Hendrick Sleep Disorders Center. *Restless Legs Syndrome Questionnaire Rating Scale*. Abilene, TX: the Center; n.d. <https://www.hendrickhealth.org/documents/content/Restless-Legs-Syndrome-Questionnaire.pdf> Accessed January 5, 2022.
36. Boston Scientific Corporation. *The AUA Symptom Score Questionnaire*. 2016. http://www.bostonscientific.com/content/dam/bostonscientific-anz/patients/downloads/Enlarged_Prostate_Symptom_Score_Questionnaire.pdf. Accessed January 5, 2022.
37. Teachers Pay Teachers [educational marketplace]. Mood scale: teaches how to scale feelings and respond in healthy ways. (n.d.). <https://www.teacherspayteachers.com/Product/Mood-Scale-Teaches-how-to-Scale-Feelings-and-Respond-in-Healthy-Ways-3838947>. Accessed January 5, 2022.
38. Tracking Happiness [website]. Happiness on a scale from 1 to 10 (How To + Implications). 2021. <https://www.trackinghappiness.com/happiness-scale-from-1-to-10/>. Accessed January 5, 2022.
39. The Depressed Duck. One simple tool to help you manage your moods. 2018. <https://thedepressedduck.com/blog/one-simple-tool-to-help-you-manage-your-moods/>. Accessed January 5, 2022.
40. Alvarez G, Cerritelli F, Urrutia G. Using the template for intervention description and replication (TIDieR) as a tool for improving the design and reporting of manual therapy interventions. *Man Ther*. 2016;24:85–89. doi:10.1016/j.math.2016.03.004
41. Alvarez G, Solà I, Sitjà-Rabert M, Fort-Vanmeerhaeghe A, Gich I, Fernández C, et al. A methodological review revealed that reporting of trials in manual therapy has not improved over time. *J Clin Epidemiol*. 2020;121:32–44. doi:10.1016/j.jclinepi.2020.01.006
42. Browne N, Bush P, Cabo F. Relieving pressure—an evaluation of Shiatsu treatments for cancer & palliative care patients in an NHS setting. *Eur J Integr Med*. 2018;21:27–33. doi:10.1016/j.eujim.2018.06.002
43. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med*. 2008;148(4):295–309. doi:10.7326/0003-4819-148-4-200802190-00008
44. Kahan BC, Morris TP. Assessing potential sources of clustering in individually randomised trials. *BMC Med Res Methodol*. 2013;13(1):1–9. doi:10.1186/1471-2288-13-58
45. Lee KJ, Thompson SG. Clustering by health professional in individually randomised trials. *BMJ*. 2005;330(7):142–144. doi:10.1136/bmj.330.7483.142
46. Croome A, Mager F. Doing research with enumerators. Oxford, UK: Oxfam Research Guidelines; 2018. doi:10.21201/2018.3576. Available from: <https://policy-practice.oxfam.org/resources/doing-research-with-enumerators-620574/>
47. Bolarinwa O. Principles and methods of validity and reliability testing of questionnaires used in social and health science researches. *Niger Postgrad Med J*. 2015;22(4):195–201. doi:10.4103/1117-1936.173959
48. Dini AP, de B. Guirardello E. Pediatric patient classification system: improvement of an instrument. *Rev da Escola Enferm*. 2014;48:787–93. doi:10.1590/S0080-623420140000500003
49. Hasson D, Arnetz B. Validation and findings comparing VAS vs. Lickert scales for psychosocial measurements. *Int Electron J Health Educ*. 2005;8:778–792.
50. Preston CC, Colman AM. Optimal number of response categories in rating scales: reliability, validity, discriminating power, and respondent preferences. *Acta Psychol*. 2000;104(1):1–5. doi:10.1016/S0001-6918(99)00050-5

51. Williams AC, Davies HT, Chadury Y. Simple pain rating scales hide complex idiosyncratic meanings. *Pain*. 2000;85(3):457–463. doi:10.1016/S0304-3959(99)00299-7
52. Bendinger T, Plunkett N. Measurement in pain medicine. *BJA Educ*. 2016;16(9):310–315. doi:10.1093/bjaed/mkw014
53. Phan NQ, Blome C, Fritz F, Gerss J, Reich A, Ebata T, et al. Assessment of pruritus intensity: prospective study on validity and reliability of the visual analogue scale, numerical rating scale and verbal rating scale in 471 patients with chronic pruritus. *Acta Derm-venereol*. 2012;92(5):502–507. doi:10.2340/00015555-1246
54. Bijur PE, Latimer CT, Gallagher EJ. Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Acad Emerg Med*. 2003;10(4):390–392. doi:10.1197/aemj.10.4.390
55. Davey HM, Barratt AL, Butow PN, Deeks JJ. A one-item question with a Likert or Visual Analog Scale adequately measured current anxiety. *J Clin Epidemiol*. 2007;60(4):356–360. doi:10.1016/j.jclinepi.2006.07.015
56. Weinrich SP, Weinrich MC. The effect of massage on pain in cancer patients. *Appl Nurs Res*. 1990;3(4):140–145. doi:10.1016/S0897-1897(05)80135-1
57. Billhult A, Bergbom I, Stener-Victorin E. Massage relieves nausea in women with breast cancer who are undergoing chemotherapy. *J Altern Complement Med*. 2007;13(1):53–58. doi:10.1089/acm.2006.6049
58. Kim H, Chang C. The effect of foot massage on anxiety response in preoperative patients undergoing total hysterectomy. *Korean J Women Health Nurs*. 2000;6(4):579–593.
59. Peterman AH, Fitchett G, Brady MJ, Hernandez L, Cella D. Measuring spiritual well-being in people with cancer: the functional assessment of chronic illness therapy–spiritual well-being scale (FACIT-Sp). *Ann Behav Med*. 2002;24(1):49–58. doi:10.1207/S15324796ABM2401_06
60. Menezes CB, Dalpiaz NR, Kiesow LG, Sperb W, Hertzberg J, Oliveira AA. Yoga and emotion regulation: a review of primary psychological outcomes and their physiological correlates. *Psychol Neurosci*. 2015;8(1):82.
61. Mc Vicar AJ, Greenwood CR, Fewell F, D’Arcy V, Chandrasekharan S, Alldridge LC. Evaluation of anxiety, salivary cortisol and melatonin secretion following reflexology treatment: a pilot study in healthy individuals. *Complement Ther Clin Pract*. 2007;13(3):137–145. doi:10.1016/j.ctcp.2006.11.001
62. Moyer CA, Seefeldt L, Mann ES, Jackley LM. Does massage therapy reduce cortisol? A comprehensive quantitative review. *J Bodyw Mov Ther*. 2011;15(1):3–14. doi:10.1016/j.jbmt.2010.06.001
63. Dowd JB, Ranjit N, Do DP, Young EA, House JS, Kaplan GA. Education and levels of salivary cortisol over the day in US adults. *Ann Behav Med*. 2011;41(1):13–20. doi:10.1007/s12160-010-9224-2
64. Benson T. Measure what we want: a taxonomy of short generic person-reported outcome and experience measures (PROMs and PREMs). *BMJ Open Qual*. 2020;9(1):e000789. doi:10.1136/bmj-joq-2019-000789
65. National Cancer Action Team. Holistic Needs Assessment for People with Cancer: a Practical Guide for Healthcare Professionals. London, UK: Royal College of Physicians London; 2014. Available from: <https://www.rcplondon.ac.uk/file/3041/download?token=nOZcbxv1>

Corresponding author: Fernando Cabo, MSc, Complementary Therapies Department, Barts Health NHS Trust, Margaret Centre, Whipps Cross Hospital, Whipps Cross Road, London E11 1NR, United Kingdom
Email: fernando.cabo@nhs.net

APPENDIX A. THE IMTEF



Location:

Date:

Integrated Medicine Treatment Evaluation Form - IMTEF

Male Female D.O.B: _____ NHS No: _____

Please tick as appropriate ✓

(if applicable or the relevant hospital or medical records number, or name if number not known)

Diagnosis

Ward based Chemotherapy Unit based Other setting *Please tick as appropriate ✓*

Which type of therapy was given?

What would you like us to help you with today?

How much of a problem is this? *Please circle as appropriate*

0 1 2 3 4 5 6 7 8 9 10
Best Worst

Can you describe your mood today? *Please circle as appropriate*

-5 -4 -3 -2 -1 0 1 2 3 4 5
Worst Neutral Best

After Treatment

How much of a problem is this after your treatment? *Please circle as appropriate*

0 1 2 3 4 5 6 7 8 9 10
Best Worst

Can you describe how your mood is after your treatment? *Please circle as appropriate*

-5 -4 -3 -2 -1 0 1 2 3 4 5
Worst Neutral Best

How much relief have you experienced from your treatment? *Please tick as appropriate ✓*

Not relieved Slightly relieved Mostly relieved Completely relieved

Please describe how your treatment has helped you today?

PATIENT COMMENTS

(Please add any additional comments here that the patient would like to make)

THERAPIST COMMENTS

Approximate duration of treatment _____ Approximate time treatment ended _____

Name of therapist:

DATA COLLECTION

Time post-treatment data was collected:

Immediately after treatment Other (please specify e.g. 1 hour after treatment) _____

Please tick as appropriate ✓

Person collecting the data:

The Therapist Other _____

Please tick as appropriate ✓

REASON FOR NOT COMPLETING THE FORM

CODES		<i>Please tick as appropriate ✓</i>
1	= Patient had gone for a procedure	<input type="checkbox"/>
2	= Communication difficulties – limited English	<input type="checkbox"/>
3	= Communication difficulties – speech impediment	<input type="checkbox"/>
4	= Treatment incomplete as the session was interrupted	<input type="checkbox"/>
5	= Patient was asleep	<input type="checkbox"/>
6	= Patient declined to give feedback on this occasion	<input type="checkbox"/>
7	= Other – please state below	<input type="checkbox"/>

APPENDIX B. REFLECTIVE QUESTION

How suitable is the IMTEF feedback form for obtaining feedback from patients on the effects of a complementary therapy treatment for a particular patient-identified problem?

- The form is very suitable for that purpose (+4)
- The form is adequate (+3)
- The form is inadequate (+2)
- The form is unsuitable for that purpose (+1)

Please tick the box selected

Please add any comments here:

APPENDIX C. HOW TO COMPLETE AN IMTEF FORM

The IMTEF treatment evaluation form has been designed to capture data about patients who have experienced a single complementary therapy treatment. These treatments may have been delivered in a variety of settings. However, the forms were designed for evaluating complementary therapy treatments given to cancer/palliative care patients in a hospital setting.

1. The IMTEF form is usually completed following consultation. The form has both **pre** and **post** treatment sections. The pre-treatment part should be completed before the treatment begins and the post-treatment section should be completed immediately after treatment or later that day. Ideally, this form should not be completed by the therapist that has delivered the treatment.
2. The **pre-treatment** section includes capturing the following data:
 - **Date of the treatment**
 - **Patient's sex**
 - **Patient's date of birth**
 - **Patient's diagnosis** (If this is a cancer patient, please add any areas of metastatic disease (cancer staging may also be added).)
 - **Patient's NHS number** (as an NHS number is patient-identifiable, the IMTEF form must be kept securely according to data protection law and organisational governance policies). In countries other than the

UK, please add a health insurance or social security number that can identify patients.

3. The pre-treatment section requires the person filling in the form to add the **location of the treatment** e.g. a hospital ward or in an out-patient clinic, such as a chemotherapy unit.
4. The **type of therapy** given that day (e.g. massage) should be entered onto the form.
5. Ask the patient to state a **symptom or concern/problem** that they would like the therapist to address. If the symptom or concern/problem stated is inappropriate for the therapist to directly address through a complementary therapy treatment (e.g. finance concern), the patient should be referred to the relevant service to help with the concern and then be encouraged to state an alternative concern that the therapist may be able to help with directly. Only one symptom or concern/problem may be identified as a treatment focus. This information should be added to the form.
6. The patient should be asked to score the **severity of the symptom or concern/problem** on a Likert scale of 0–10; with 10 being the worst (ensure this is explained to the patient). Only whole numbers may be chosen on any of the numerical scales (e.g. not mid-way between one score and another). The relevant score should then be circled on the form.
7. The patient should be asked to **describe their mood** prior to treatment on a scale ranging from -5 (worst) to +5 (best). The relevant score should then be circled on the form. The '0' on the scale has been listed on the form as the 'neutral' point – where the patient's mood is described as 'even' (ensure this is explained to the patient).
8. The **post-treatment** section of the form requires the patient to score the **severity of the symptom or concern/problem** after the treatment has ended. The relevant score should then be circled on the form.
9. The patient should be asked to **describe their mood** post-treatment. The relevant score should then be circled on the form.
10. An additional question about how much **relief** the patient experienced

from their symptom is also asked post-treatment. This question should be asked where the patient has a clearly defined physical symptom such as nausea. This question need not be asked when the patient has no clear symptom or concern/problem, and only wants to relax. The patient should determine which option of four is the closest to their post-treatment experience; the scale ranges from 'not relieved' to 'completely relieved'. The relevant answer should then be identified by ticking the box on the form.

11. The patient should be asked to put into words **how the treatment has helped** them today. For example, the patient may add that they also feel 'sleepy' after treatment and this may correlate directly to the reduction in severity of the symptom or concern/problem noted previously. This should be added to the relevant free text box on the form.
12. There is a section at the top of page 2 entitled **Additional Patient Comments**. This section is for recording any unsolicited comments made by the patient. For example, the patient may ask for additional treatments at a later date. This question should not be routinely asked. Patients' responses should be added to the relevant free text box on the form.
13. The section headed '**Therapist Comments**' requires the staff member completing the form to record the approximate **length of the treatment** and **the approximate time the treatment ended**. There is also a free text box where the therapist can leave other relevant information.
14. The section headed '**Data Collection**' requires the staff member completing the form to state the **time when the post –treatment data was collected** and state **who is collecting the data** (i.e. the therapist or an enumerator).
15. The final section on the form requires the person filling in the form to note reasons why an evaluation form may be left incomplete. The codes for non-completion of the form range from the session being interrupted, so the treatment was not undertaken, or the patient had declined to give feedback. The relevant code should be identified on the form.
16. The forms should be used as designed and not changed in any way.