ORIGINAL ARTICLE

A Pragmatic Observational Feasibility Study on Integrated Treatment for Musculoskeletal Disorders: Design and Protocol

Xiaoyang Hu[1], John Hughes[2], Peter Fisher[2], Ava Lorenc[1], Rachel Purtell[3], A-La Park[4], and Nicola Robinson[1]

ABSTRACT **Background:** Musculoskeletal disorders (MSD) comprise a wide range of conditions, associated with an enormous pain and impaired mobility, and are affecting people's lives and work. Management of musculoskeletal disorders typically involves a multidisciplinary team approach. Positive findings have been found in previous studies evaluating the effectiveness of complementary therapies, though little attention has been paid to evaluating of the effectiveness of integrated packages of care combining conventional and complementary approaches for musculoskeletal conditions in a National Health Service (NHS) setting. **Objective:** To determine the feasibility of all aspects of a pragmatic observational study designed: (1) to evaluate the effectiveness and cost effectiveness of integrated treatments for MSDs in an integrated NHS hospital in the UK; (2) to determine the acceptability of the study design and research process to patients; (3) to explore patients' expectation and experience of receiving integrated treatments. **Methods:** This is an observational feasibility study, with 1-year recruitment and 1-year follow-up, conducted in Royal London Hospital for Integrated Medicine, University College London Hospital Trust, UK. All eligible patients with MSDs newly referred to the hospital were included in the study. Interventions are integrated packages of care (conventional and complementary) as currently provided in the hospital. SF-36™ Health Survey, short form Brief Pain Inventory, Visual Analogue Scale, and modified Client Service Receipt Inventory will be assessed at 4/5 time points. Semi-structured interview/focus group will be carried out before treatment, and 1 year after commence of treatment. **Discussion:** We intend to conduct a pragmatic observational study of integrated medical treatment of MSDs at a public sector hospital. It will inform the design of a future trial including recruitment, retention, suitability of the outcome measures and patients experiences.

KEYWORDS integrated medicine, musculoskeletal disorders, feasibility study, mixed method

Musculoskeletal disorders (MSDs) comprise a wide range of conditions, associated with an enormous pain and impaired mobility, and are affecting people's lives and work. It is reported that 70%–84% of adults in the UK experience nonspecific low back pain[(1)] and 70% experience neck pain[(2)] during their lifetime. The incidence of MSDs appears to be increasing, with a corresponding impact on primary health care provision.[(3)] MSDs treatments cost $389 million to the retail industry in the US in 2007.[(4)] Annually in the UK they cost approximately £7.4 billion and cause £9.5 million lost working days.[(5)]

Management of MSDs typically involves a multidisciplinary team approach, including reduction in workload, increased rest, stress management, behavioural intervention and physiotherapy. Drug therapies include simple analgseics such as paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, topically or systemically, opioids and tricyclic antidepressants; as well as surgery. Complementary and alternative medicine (CAM) is commonly used to treat musculoskeletal conditions, especially pain such as back pain, neck pain and shoulder pain.[(6-8)] The National Institute for Health and Clinical Excellences's (NICE) guideline on low back pain recommends consideration of manual therapy and acupuncture, traditionally considered CAM therapies.[(9)]

A recent systematic review reported the 12-month prevalence of any use and visits to CAM practitioners in

1. Faculty of Health and Social Care, London South Bank University, London, SE1 0AA, UK; 2. Royal London Hospital for Integrated Medicine, University College London Hospital National Health Service Trust, London, WC1N 3HR, UK; 3. Patient representative; 4. Personal Social Services Research Unit, Health and Social Care, the London School of Economics and Political Science, London, WC2A 2AE, UK
Correspondence to: Dr. Xiaoyang Hu, Tel: 20-78158350, Fax: 20-78158490
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15 countries, with prevalence ranging from 9.8%–76.0% for the use of any CAM and 1.8%–48.7% for visits to CAM practitioners, respectively.[10] An increasing number of English primary care practitioners offer CAM to their patients rising from 39% in 1995 to 50% in 2001.[6]

The Royal London Hospital for Integrated Medicine (RLHIM) is the largest public sector provider of integrated medicine in Europe and is part of University College London Hospitals (UCLH) National Health Service (NHS) Foundation Trust. MSDs are the most frequent reason for referral. In 2010, the hospital received over 15,000 patient referrals, of which 3,633 cases (24.2%) were MSDs referrals.

The effectiveness of many complementary therapies for MSDs has been explored in previous studies, with some positive findings.[11-14] However, little attention has been paid to evaluating of the effectiveness of integrated packages of care combining conventional and complementary approaches for MSDs in an NHS setting. Therefore, a feasibility study is required to pilot the study design in order to inform a future definitive trial.

This study aims to determine the feasibility of all aspects of a pragmatic observational study designed: (1) to evaluate the effectiveness and cost effectiveness of integrated treatments for MSDs in an integrated NHS hospital in the UK; (2) to determine the acceptability of the study design and research process to patients; (3) to explore patients' expectation and experience of receiving integrated treatments.

METHODS

Setting and Design

This study will be conducted in the outpatient department at the RLHIM. It will use a pragmatic observational, mixed methods approach (quantitative and qualitative methods), with 1-year follow-up.

Ethical Approval

Ethical approval for the study was obtained from City and East London Research Ethics Committee (REC reference number: 12/LO/1341). Anonymous data will be held securely and transferred only between the research team members.

Inclusion and Exclusion Criteria

This study will include all eligible patients with MSDs attending RLHIM in a 12-month period from January 2013 to January 2014. Table 1 shows the inclusion/exclusion criteria for the study. All eligible patients who give informed consent and indicate they are willing to participate in the study over the 12-month period will be recruited.

Table 1. Study Eligibility Criteria

Inclusion criteria	Exclusion criteria
1. *New referrals to RLHIM for MSDs; 2. Patients who are at least 16 years old of both gender; 3. Patients who have a primary diagnosis of ICD-10 codes-musculoskeletal system and connective tissue; 4. Patients who are able to take part in the study for 1 year.	1. Patients who are unwilling to take part in the study; 2. Patients who are unable to speak English and therefore unable to understand the patient consent form or patient information form; 3. Patients who have severe progressive disorders with life threatening condition or poor prognosis; 4. Patients who have cognitive impairment such as dementia or psychological disorders.

Notes: *Including all MSDs patients who have had treatment for MSDs previously but are now presenting for a new episode of care. Either a single MSDs diagnosis or with a combination MSDs diagnoses will be included; ICD, international classification of diseases

Qualitative data will be collected both before and after treatment in a manner which will ensure that the views of a range of participants are reflected. Patients will be purposively selected on the basis of their expectations of benefit from the treatment, age and gender (at 1st interview, before treatment). A second sample of participants will be purposively selected following treatment based on the results of their SF-36™ Health Survey (SF-36), short form Brief Pain Inventory (BPI-sf), Patient Expectation Questionnaire (PEQ) scores, medical condition, age and gender. This data will be collected at the 2nd interview or focus group at 1 year starting treatment.

Routine Practice for MSDs at RLHIM

Patients who present with MSDs typically receive integrated packages of care from RLHIM. The integrated packages of care combine conventional and complementary approaches, including dry needling and acupuncture, trigger point therapy, prolotherapy (injections to ligaments), homeopathy, phytothera, electrotherapies; medical manipulation, orthotics, cognitive behavioural therapy, occupational therapy, musculoskeletal physiotherapy, nutritional and dietary assessment and advice.

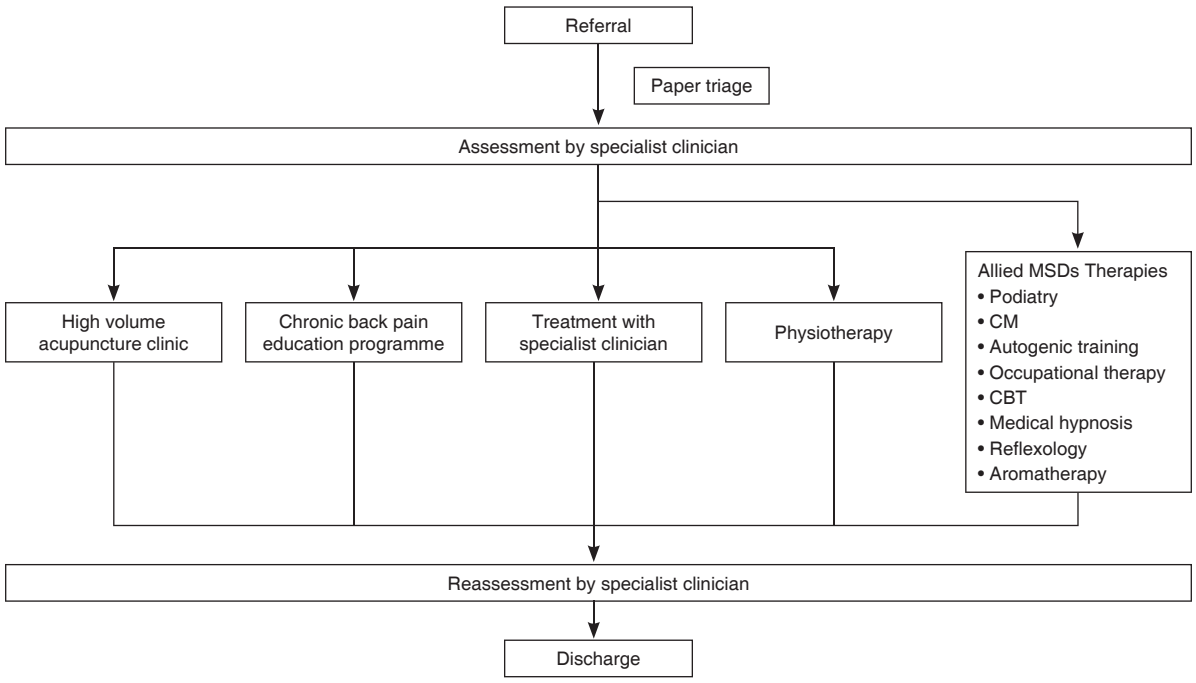

Figure 1. Musculoskeletal Care Pathway at RLHIM for Integrated Medicine
Notes: CM: Chinese medicine; CBT: cognitive behaviour therapy

As per routine standard practice, all musculoskeletal referrals to the RLHIM will be triaged by a specialist clinician and referred to various departments (Figure 1). All patients will be reassessed by a specialist clinician before being discharge.

Participant Recruitment and Flow

Figure 2 details the process of recruitment and data collection procedures for the feasibility study. Patients will be screened using the inclusion/exclusion criteria. Eligible patients will receive a Patient Information Sheet (PIS) and invitation letter, and a reminder about the study from the patient services department when arranging their hospital appointment. Patients will be further screened on the phone by the chief investigator (CI). Those providing verbal consent will be sent a questionnaire package including consent form, sociodemographic questionnaire, PEQ with a reply paid envelope to patients who are happy to be contacted. Those patients who provide written consent and return the questionnaires will be contacted by the CI to arrange a face-to-face meeting prior to their 1st hospital appointment.

Patients who present with MSDs typically receive packages of care from RLHIM. During the 1st appointment, some patients receive treatment immediately, others may receive an initial treatment but then have to wait before the beginning of a course of treatment.

OUTCOME MEASURES

A range of outcome measures will be employed in order to determine their appropriateness and acceptability for accessing integrated packages of care for patients with MSDs.

Sociodemographic Questionnaire

The sociodemographic questionnaire includes: level of education, occupational status, first language, religious affiliation and ethnic origin. It takes approximately 2 min to complete, and will be administered once in the period between the 1st appointment being booked and attending this appointment.

PEQ

As expectation of benefit has been shown to impact on clinical effectiveness,[15] we have developed a PEQ to assess patients' expectation of benefit from their integrated treatment, and how much faith they have in complementary therapies in general, both measured on 10-point ordinal scales. The PEQ takes approximately 2 min to complete, and will be administered once, at the same time as the

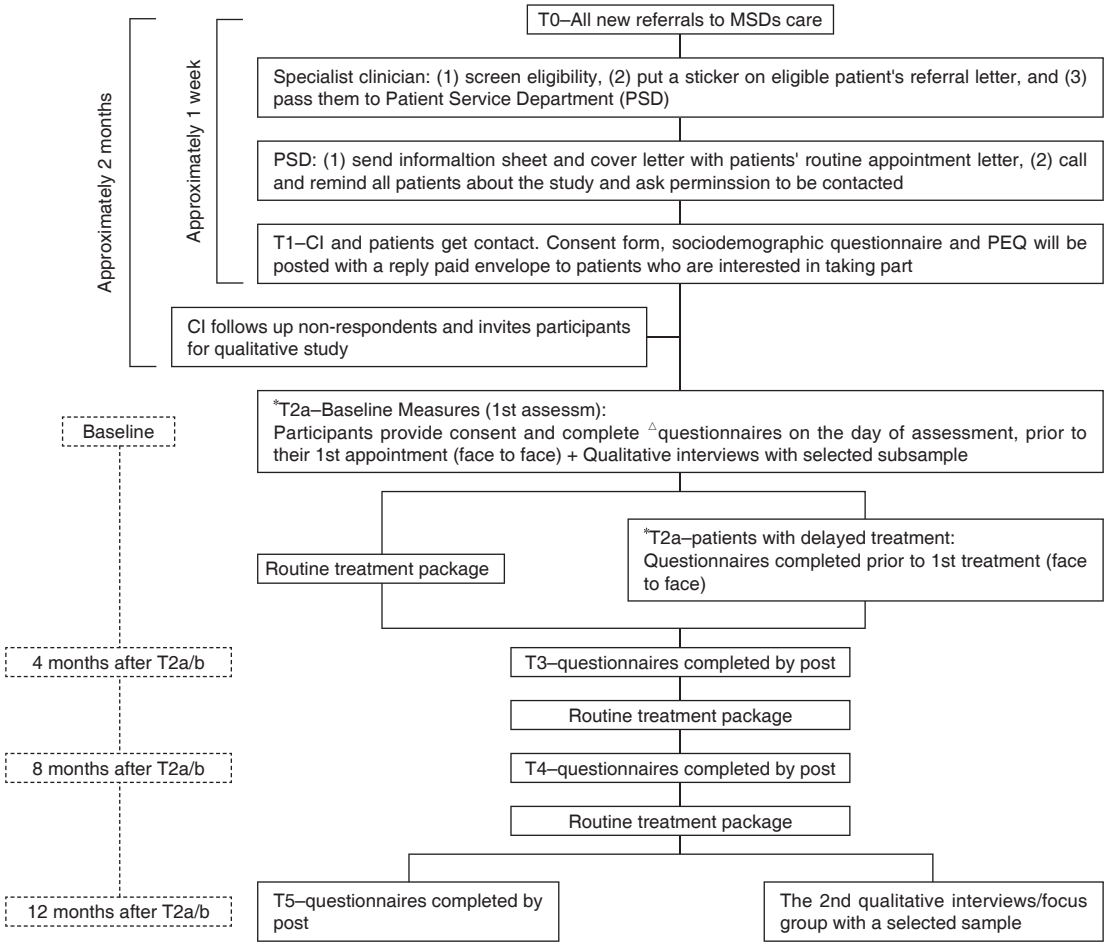

Figure 2. Participant Flow

Notes: *In routine practice, some patients may have one-off treatment or commence their treatment immediately at T2a, some patients may have to wait for their treatment. For those who are put on the waiting list (up to 5 months), an additional evaluation will be administered at T2b before their 1st treatment. △Questionnaires include SF-36, BPI-sf, Visual Analogue Scale and modified Client Service Receipt Inventory

sociodemographic questionnaire.

Primary Outcome Measures

The SF-36—Bodily Pain Subscale

The SF-36 is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. The internal consistency of the SF-36 had been extensively evaluated with most studies finding a reliability coefficient (Cronbach's alpha) over 0.80.[16]

Bodily pain is one dimension of SF-36 consisting of two questions. The bodily pain subscale is an accepted, validated and reliable sub-scale, useful for making comparisons across populations.[17]

Secondary Outcome Measures

The SF-36 —Other Dimensions

In addition to the SF-36 bodily pain dimension, there are 34 questions on physical function, physical role, general health, and mental health, emotional role, social function and vitality. SF-36 has been used and validated with numerous studies in a variety of patient populations, including patients with MSDs.[18-22] This questionnaire has also been suggested for routine use within the NHS.[23] The SF-36 (including SF-36 Bodily Pain Dimension) takes approximately 10 min to complete.

BPI-sf

The BPI-sf is a valid and reliable tool for evaluating pain status.[24,25] It has been used widely for various kind of pain, especially in musculoskeletal pain.[26-29] It includes 9 questions and provides information on the intensity of pain, along with the degree to which the pain interferes with everyday

functioning. The internal consistency of the BPI-sf has been extensively evaluated with studies finding a reliability coefficient (Cronbach's alpha) of 0.77 to 0.91.[30] Numerous studies have used the BPI-sf in a variety of patient populations, including patients with MSDs.[31] It is routinely used for MSDs at RLHIM. The BPI-sf takes approximately 5 min to complete.

Visual Analogue Scale

Visual Analogue Scale (VAS) is a commonly used outcome measurement to monitor variations in intensity of pain. It will provide additional confirmation together with BPI-sf and SF-36 Bodily Pain subscale to validate patients' reports of pain. The VAS takes less than 1 min to complete.

Modified Client Service Receipt Inventory

Health and social care service utilization will be explored by asking participants about quantity/frequency of service use. The Client Service Receipt Inventory (CSRI) is an internally validated instrument.[32] A modified version of the CSRI (mCSRI) has been designed to collect retrospective data on the impact of integrated medicine approaches on use of our health and social care services. The mCSRI takes approximately 10 min to complete.

Qualitative Study

In the 1st semi-structured interview, a interview schedule with a series of prepared, open-ended statements will cover the participants' condition, treatments previously used, referral process to RLHIM and their expectation of the integrated treatments. The 2nd semi-structured interview or focus group will cover patient's experiences of the integrated treatments they received at the RLHIM, their experiences of participating in the study, including recruitment, drop-out and compliance, acceptability of the study design and outcome measures. Both interviews and focus groups will last 60 min, and will be digitally recorded and transcribed verbatim.

Sample Size

Although a feasibility study does not require a sample size calculation, we hope to recruit 150 patients and anticipate that this will provide a sufficiently large enough sample to capture the range of patients and conditions presenting at the RLHIM.

Previously at RLHIM a pragmatic observational study was carried out on a group of 152 patients (presenting for a variety of conditions) receiving a course of autogenic training over 12 months.[33] This project demonstrated the feasibility of this approach and the ability to recruit and demonstrate change after completing the autogenic training programme at RLHIM. It is anticipated that there will be more eligible patients in the proposed study as MSDs are the group of conditions mostly frequently presenting at the hospital.

There were 311 new MSDs referrals in 2010 to the RLHIM and estimating that approximately 50% would be ineligible or do not consent to take part in the study, it is anticipated that there will about 150 eligible patients. Data on patients who drop out during the study will be collected for further comparisons.

For the qualitative study, a limit of 30 patients was set for each of the two nested qualitative studies, as it is anticipated that this will be a sufficient sample size to ensure theoretical saturation of emergent categories and themes.[34]

DATA COLLECTION

Data Collection on Feasibility

During recruitment, data will be recorded on number of past/new referrals, eligible patients for the study, number of patients consenting/declining to take part, and reasons for not participating.

At the end of the study, attendance for appointments, patient follow-up and drop-out/completion rates will be generated from treatment logs. Rates of completion of the outcome measures, data collection and analysis will be explored by the CI. The study timeline as measured by the time taken to recruit and complete the study will also be evaluated.

Quantitative Data Collection

Data will be collected at 4 time points (5 if patients have delayed treatment, Table 2): T1 (mail) after an appointment is arranged but before the patient has attended T2a before their 1st treatment; T2b (if treatment is delayed, face to face) immediately prior to starting their package of treatment; T3, T4, (mail) at 4, 8, 12 months respectively after T2a/b; T5 (mail or interview/focus group for subset) 12 months after T2a/b. The CI will post a copy of the SF36, BPI-

Table 2. Schedule of Outcome Measures

Measurements	Waiting time between referral letter and treatment initiation (T1)	Before initiation of RLHIM treatment (T2a)	Before initiation of RLHIM treatment (T2b)	4 months after T2a/b (T3)	8 months after T2a/b (T4)	12 months after T2a/b (T5)
Sociodemographics	X					
PEQ	X					
SF-36		X	X	X	X	X
BPI-sf		X	X	X	X	X
VAS		X	X	X	X	X
mCSRI		X	X	X	X	X

Note: X rpresents the time point at which this questionnaire data will be collected

sf, VAS and mCSRI to patients with a reply paid envelope. A list of the outcome measures schedule is given (Table 2).

Qualitative Data Collection

Qualitative data will be collected at T2a and T5. Interview/focus groups will be conducted at RLHIM, patients homes, or other location convenient for participating patients.

DATA ANALYSIS

The analysis of data (both qualitative and quantitative) will be undertaken by the CI under the supervision of the research team.

Frequency Data Analysis

Frequency data on the number of past/new referrals, eligible patients for the study, number of patients consenting to take part and with explanation of reasons in detail will be manually entered into Microsoft Excel. A record of all patients will be kept on: their attendance for treatments, the treatments provided, and the completion of questionnaires and interview/ focus groups with dates specified. A timeline of the whole pilot will inform the future study protocol.

Data Analysis for the Quantitative Pilot Trial

Data from the sociodemographic questionnaire, SF36, BPI-sf, VAS and mCSRI will be entered in Excel, and analysed using Statistical Packages for Social Sciences (SPSS) version 18 using appropriate between-group tests.

The primary time period is the change in scores over a 4-month period after starting definitive treatment and at 12 month follow-up assessment, in order to assess the feasibility of measuring the potential long-term treatment effect. Data on the feasibility of the study design including recruitment, compliance, follow-up, outcome measures, time scale and acceptability to patients and clinicians will be used to develop a protocol for a full trial. In order to calculate the sample size for the full trial, data will be used to calculate the effect size. Exploratory data analysis will be conducted on all the relevant parameters. If the data is normally distributed, an ANOVA will be conducted comparing scores in mean of different time points, followed by Pearson correlation and regression test for possible combinations. If appropriate and if there are sufficient numbers, sub analysis will be conducted to evaluate the differences in improvement between different categories of patients, for example: patients with various MSDs diagnosis; presence of one or multiple MSDs; sociodemographic characteristics; package of care received, including group treatment or one-to-one clinics and number of different therapies received. Differences between patients who do not complete their course of treatment and completers will be evaluated. Sensitivity analyses will be performed by varying a wide range of parameters in terms of costs.

Patients are routinely discharged from the hospital if they fail to attend for an appointment on two consecutive occasions. Intention to treat analysis using last value carried forward will be used, so if patients are discharged before completing treatment or are otherwise lost to follow-up, all the data collected up to the last point will be used. This helps in preventing skewed data and those data will be collected for a subgroup analysis, to evaluate the differences between those patients and those who consistently come to the clinics.

Data Analysis for the Interview/Focus Group

The semi-structured interviews and focus groups with patients will be digitally recorded and transcribed

verbatim. Qualitative data will be analysed thematically and major categories and themes identified using NVivo10.

DISCUSSION

This study is developed based on data from everyday practice at the RLHIM. Based on this we plan a feasibility study to evaluate the effectiveness and cost effectiveness of the integrated package of treatment for MSDs provided at the RLHIM. We plan to recruit 150 patients by January 2014.

There is a dearth of published research evaluating the impact of integrated treatments for MSDs in a NHS setting. This research will inform all aspects of the design of a future trial including recruitment, retention, suitability of the outcome measures, patients views and experience. A definitive trial is important because these conditions are highly prevalent and complementary therapies often used by patients, although usually outside NHS settings. Such a trial would improve policy, inform guidelines and decision-making for MSDs practitioners and MSDs patients; provide policymakers/commissioners with economic evidence, which may facilitate optimal resource allocation decisions; and to inform clinical practice for future patient care at the RLHIM and elsewhere by suggesting which treatment combinations are associated with the best outcomes for MSDs patients.

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Conflict of Interest Statement

We acknowledge that there is a patient and staff from RLHIM involved in this study, however, there is no conflict of interest as there is no direct financial or other connections with other people or organizations or that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service and/ or company that could be constructed as influencing the position presented in, or the review of, the manuscript.

Disclosure Statement

No competing financial interests exist.

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