

Massage Therapy Research Fund (MTRF)



Project Report - FINAL

Current Date:	February 28, 2017
Project completion deadline:	December 31, 2016
Extension granted:	December 31, 2016
Project Title:	Development of a taxonomy of adverse events in massage therapy: a modified Delphi consensus study
Amount of grant:	19479.00
Year grant awarded:	2013/2014
Institution:	University of Saskatchewan
Principal Investigator (name only):	Anne Leis
Co-Investigators (names only):	Donelda Gowan-Moody

THE REPORT CONTENT:

Section 1 - Project overview. Please devote a maximum of one page to background, rationale and objectives, with the balance to focus on methods and outcomes. (maximum 4 pages).

Section 2 - Did the project take place as proposed? If not, briefly indicate difficulties encountered and adaptations made (maximum 1 page).

Section 3 – Information dissemination. Please provide the information dissemination plan related to the project findings. Please list all completed activities and planned activities (manuscripts, reports, conference presentations, seminars, workshops etc).

Section 4 - Project summaries. Please provide two project summaries, as follows:

- a) Lay language summary (maximum 100 words)
- b) Scientific abstract (maximum 250 words)

**Submitted the completed final report to Ania Kania-Richmond at
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Section 1. Project overview

There is a dearth of information regarding harm in massage therapy. A review of the literature on adverse events and risk of harm in manual therapy research shows the importance of clarity in defining and describing terms (1-5) and there are contrasting views with respect to what constitutes harm (5). Interestingly, most of what has been investigated regarding harm in manual therapies excludes massage therapy. Massage therapy is sometimes omitted for consideration in investigating potential harm in clinical practice explicitly, often for reasons of lack of regulated health provider status (2, 6) or implicitly in studies only including physiotherapists, chiropractors, or osteopaths (3, 4).

Dated information about physician and mainstream health care providers perceptions about potential benefits and risk in massage therapy suggests that many physicians support massage therapy as likely to be helpful and unlikely to be harmful (7-9). Respondents reportedly offered "being too aggressive" and "practicing beyond their area of expertise" as possible ways harm could come about (9). Physician referral rates are high relative to other therapies considered to be complementary or alternative medicine (10).

Possible risk to the public associated with exposure to massage has been assumed to include potential physical, financial or emotional/psychological harm that could result from incompetent or unethical practice (11). Posadzki and Ernst (2013) report on eighteen primary cases published from December 2001 to May 2012 in a recent systematic review on the safety of massage therapy. The events reported in the literature include vertebral artery dissection, stroke, spinal cord injury, venous thromboembolism, paralysis, spinal fracture, and organ damage (12). In an earlier review, Ernst (2003) concludes that massage is not entirely risk free but the incidence of serious adverse events is suspected to be low. Under-reporting of adverse effects is considered likely (13).

Rationale

Little is known about the values within the field of massage therapy with respect to the meaning of risk of harm or adverse events. A massage-therapy specific adverse event taxonomy to guide regulators, profession leaders, educators, and practitioners in discussion about safety in massage therapy is absent from the current literature. Without a clear understanding of adverse events in massage therapy there can be no framework from which to inform decision-making in future epidemiological studies.

Objectives. 1) To explore massage therapy (MT) regulators' views on patient safety and adverse events (AEs) in the practice of MT

2A. To explore taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events) in existing published literature on massage and manual therapies.

2B. To compare available massage and manual therapy patient safety incident taxonomies with an internationally developed framework in order to summarize and collate the results

3. To reflect on how the findings of the study aid the patient safety culture of the profession of massage therapy in Canada, including knowledge translation and transfer.

Methods and Outcomes

Focus Group Methods

A focus group (10 participants) comprised of College of Massage Therapists of British Columbia (CMTBC) Board and staff in attendance at a CMTBC AGM was used to explore participants views on the nature of AE in MT. The data was collected with audio recordings and discussion notes taken by DGM who moderated the focus group with questions generated from discussion between the PI and co-applicant. Thematic content analysis was used to describe major themes and sub-themes in the data. Ethics approval was obtained for the focus group investigation from the BEH REB at the University of Saskatchewan.

Scoping Review Methods

A scoping review or scoping study “is a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge” (14). In the tradition of Arksey and O'Malley (2005), the goal is to rigorously collect and summarize existing research evidence to facilitate its effective use. This scoping study is comprised of six stages or steps: identify the research question, identify relevant studies, select the studies, chart the data, collate, summarize and report on the results, and the final step is stakeholder consultation.

In this scoping review we asked: what is the current knowledge and practice of defining and classifying patient safety incidents (adverse events) in massage and manual therapies in the literature regarding patient outcomes as characterized by the WHO minimum information model regarding type of harm, degree of harm, and social and/or economic impact?

Ten peer-reviewed electronic databases limited to English as well as bibliographies, citations and key authors were searched. Inclusion/exclusion criteria were applied to all records independently by two reviewers and qualitative information was extracted and charted.

Stakeholder Consultation Methods

While consultation with stakeholders took place from development of the purpose and objectives of the study, the final consultation exercise was to solicit feedback about the study findings and direction for further dissemination. The participants of the stakeholder consultation exercise were drawn from the attendees of an oral presentation of the scoping review at the 9th Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (INCAM) Symposium in Toronto, Ontario and attendees of a meeting of the Massage Therapy Special Interest Group (MT-SIG) held in conjunction with the symposium.

Outcomes

Summary of Results of the Focus Group Investigation

The main finding of the qualitative study with the focus group was the importance participants placed on a two-fold conceptualization of trust: the public's trust in massage therapists' capacity to promote their health and the public's trust that a system of accountability safeguards their welfare. The regulators were confident that RMTs have demonstrated the capacity to support the well-being of their patients and that the legislatively derived authority of the College promotes public safety.

Patient safety in massage therapy can usefully be characterized as a pantheon built on a foundation of trust, and supported by three pillars: a well-defined role for the massage therapist, clear treatment expectations, and protection of patient vulnerability. The structure and its component parts serve to reduce the potential risks inherent in the delivery of healthcare. It also forms and binds the integrity of the profession, its members, and its governing organizations.

MT regulator participants view the therapist's role as that of a healthcare provider entrusted to deliver safe and effective care. Patient expectations of trust and therapists' responsibility to uphold that trust are seen as critical, especially when treatment might be painful. Massage therapy patients are thought to be uniquely vulnerable due to the nature of the therapeutic encounter: extended personalized time, a state of undress, and physical touch all serve to exacerbate risks to well-being if not safeguarded by a professional massage therapist who is bound to adhere to practice standards enforceable by a legislatively-defined authority.

Main Findings of the Scoping Review

The titles of 967 articles were identified and their abstracts reviewed; 67 articles were retrieved and read. 14 of them met the final inclusion criteria and were retained for analysis. Study designs were varied with survey (questionnaires) most common. The included studies were conducted in several Western countries with Canada and the United Kingdom most common.

This scoping review led to four key findings as well as the generation of themes that illustrate. First, the term "adverse event" is the most commonly used term in patient safety research in the manual therapies included in this review. Second, symptoms' duration, severity, intensity, and impact on function are the common elements used in the creation of taxonomies to describe patient outcomes in the study of potential harm and thus are consistent with the WHO International Patient Safety Framework and the Minimum Information Model for reporting on patient safety incidents. Third, numeric rating scales are useful means of describing and classifying levels of severity, intensity, and impact on function for negative as well as positive patient outcomes. Fourth, there is a lack of uniform definition and taxonomy to describe adverse patient outcomes in patient safety research in professions that provide manual therapy in regular patient management.

Stakeholder Consultation Outcomes Stakeholders responses indicated that the study was interesting and likely of value to the profession of massage therapy. Stakeholders also suggested that a glossary of WHO preferred terms should be distributed to practitioners and educators. Another suggestion was to publish knowledge from the study in popular trade magazines (e.g. *Massage Therapy Canada*) for wide and easily accessible knowledge transfer and research dissemination.

Section 2. Did the project take place as proposed? max one page

Initially, a Delphi survey was proposed as a means of generating a taxonomy of patient safety incidents in massage therapy. As the study progressed it became evident that more information would need to be provided to future participants of a Delphi survey and that a mixed methods research project would best serve this need. The project was expanded beyond the initial proposal to include a focus group, a formal scoping review and a stakeholder consultation exercise for knowledge translation. An additional manuscript was prepared in a paper-based dissertation and for submission to a peer-reviewed journal when only one paper was originally proposed. Also, an article for a trade magazine for knowledge translation has been included for knowledge translation but was not proposed in the project description and grant application. We gratefully acknowledge the support of the grant for supporting the expanded scope of this project and its timeline.

Section 3. Information Dissemination Please provide the information dissemination plan related to the project findings. Please list all completed activities and planned activities (manuscripts, reports, conference presentations, seminars, workshops etc).

Planned Activities

- An abstract has been submitted to the 38th Annual Canadian Pain Society Scientific Meeting. Halifax, NS, May 23-26, 2017
- An article describing the stakeholder consultation exercises and results is being prepared for Massage Therapy Canada magazine.
- A manuscript based on the focus group findings has been written and will be submitted for peer-review.
- A manuscript based on the scoping study has been written and will be submitted for peer-review.

Current Dissemination

A dissertation based on the thesis work funded by the MTRF has been written. This work will be submitted to the College of Graduate and Postdoctoral Studies in partial fulfillment of the requirements for the degree of Doctorate of Philosophy.

Oral Presentations

- Gowan-Moody D, Baskwill A, Leis A. Exploring massage and manual therapy patient safety incident (adverse event) taxonomies: a scoping review. 2016 INCAM Research Symposium: Expanding Person-Centred Care through Integrative Health Research. November 18-19, 2016. Toronto, Ontario.
- Gowan-Moody, D. Understanding adverse events in massage therapy: a focus group investigation. Department of Community Health & Epidemiology. Student Research Day. Royal University Hospital SaskTel Theatre. February 5, 2015. Saskatoon, Saskatchewan.
- Gowan-Moody, D. Are we playing fast and loose with patient safety in MT? A review of the literature. 2nd MTAS Interdisciplinary Research Symposium. March 28th, 2015 Saskatoon, Saskatchewan.
- Gowan-Moody, D. Patient safety in massage therapy: a literature review. Department of Community Health & Epidemiology. Student Research Day. Royal University Hospital SaskTel Theatre. February 13, 2014, Saskatoon, Saskatchewan.
- Gowan-Moody D, Leis A. Adverse events in massage therapy: perspectives from a focus group IN-CAM Research Symposium: The Next Wave of Complementary and Integrative Medicine and Health Care Research. Nov 6-8, 2014, Calgary, Alberta.

Poster presentations on the research findings:

- Exploring Pain-related Patient Safety Incidents (Adverse Events) in Massage Therapy. The International Congress on Integrative Medicine and Health (ICIMH), Las Vegas, Nevada, USA May 17–20, 2016
- Gowan-Moody D, Leis A. Can it hurt? Reports of pain-related adverse events in massage therapy. The Canadian Pain Society 37th Scientific Meeting, May 24-27, 2016. Vancouver, British Columbia.
- Gowan-Moody D, Leis A. Can it hurt? Reports of pain-related adverse events in massage therapy. 6th Conference on Implementing Best Practices for Pain Management in Saskatchewan. November 3-4, 2016. Regina, Saskatchewan.

Abstracts published:

- Gowan-Moody D, Baskwill A, Leis A. Exploring massage and manual therapy patient safety incident (adverse event) taxonomies: a scoping review in Boon H, Gaboury I, Balneaves LG, Tsui T, Ng J, Bozinovski N (eds) 2016 INCAM Research Symposium: Expanding Person-Centred Care through Integrative Health Research *Journal of Complementary and Integrative Medicine*. Volume 13, Issue 4, Pages eA1–eA27. October 2016
- Gowan-Moody D, Leis A. Exploring Pain-related Patient Safety Incidents (Adverse Events) in Massage Therapy. The International Congress on Integrative Medicine and Health (ICIMH), Las Vegas, Nevada, USA *May 17–20, 2016*. *The Journal of Alternative and Complementary Medicine*. June 2016, 22(6): A1-A142
- Gowan-Moody D, Leis A. Adverse events in massage therapy: perspectives from a focus group (eA38) in Boon H, Kania-Richmond A, Verhoef M, Tsui T, Danelesko E (eds) 2014 IN-CAM

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Lay Language Summary

Use and evidence of the benefits of massage therapy is growing, but safety has been understudied. This study asked questions about patient safety issues and how they are identified and classified. Information was drawn from expert sources that included regulators, the research literature, and professional association leaders and massage therapists in Canada. The most important issue identified was that harm can occur but what is considered a harmful outcome (or not) is not clear. Legislated self-regulation plays a role in keeping massage therapy safe. Knowing more about safety issues will help patients, therapists, and regulators report and learn from incidents.

Scientific Abstract

Background

A dearth of information on patient safety in massage therapy (MT) persists. The views of experts are unknown while classification of adverse events (AEs) lacks standardization. The objectives were to explore: 1) MT regulators' views on patient safety; 2) taxonomies for describing AEs and 3) stakeholders views

Methods

A mixed methods approach included a focus group investigation with 10 members of the College of Massage Therapists of British Columbia. Thematic content analysis was used to describe themes. Then, ten peer-reviewed databases limited to English as well as bibliographies, citations and key authors were searched. Inclusion/exclusion criteria were applied to all records independently by two reviewers and qualitative information was extracted and charted. Consultation with stakeholders took place throughout the study.

Results

Massage therapy can usefully be characterized as a pantheon built on a foundation of trust, and supported by three pillars: a well-defined role for the massage therapist, clear treatment

expectations, and protection of unique patient vulnerability. In the scoping study, the titles of 967 articles were identified and their abstracts reviewed; 67 articles were retrieved and read. 14 of them met the final inclusion criteria and were retained for analysis. Mapping shows shared elements of AE classification conform to international standards but a lack of uniformity. Stakeholders recommended translating this new knowledge widely.

Conclusions

A unique culture of patient safety in Canadian MT appears to be emerging that manages the potential risks inherent in the delivery of healthcare. Current taxonomic models can be made meaningful for MT with further scholarship, research and engagement with stakeholders.

1. Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: a systematic review. *Manual Ther.* 2010 Aug;15(4):355-63. PubMed PMID: 20097115. Epub 2010/01/26. eng.
2. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *Manual Ther.* 2010 Feb;15(1):2-6. PubMed PMID: 19443262.
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5. Carlesso LC, MacDermid JC, Santaguida LP. Standardization of adverse event terminology and reporting in orthopaedic physical therapy: Application to the cervical spine. *Journal of Orthopaedic and Sports Physical Therapy.* 2010 //;40(8):455-63.
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10. Ezzo J. What Can Be Learned from Cochrane Systematic Reviews of Massage That Can Guide Future Research? *J Altern Complement Med*. 2007;13(2):291-5.
11. Gowan-Moody D, Baskwill A. Report on Policy Issues Concerning the Regulation of Massage Therapy in Canada. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), 2006 May. Report No.
12. Posadzki P, Ernst E. The safety of massage therapy: an update of a systematic review. *Focus Alternat Complement Therap*. 2013;18(1):27-32.
13. Ernst E. The safety of massage therapy. *Rheumatology*. 2003;42:1101-6.
14. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol*. 2014 12//;67(12):1291-4.