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**Preliminary development of a complex intervention for osteopathic management of dysfunctional breathing**

Short Title: Osteopathic Management of Dysfunctional Breathing

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# Preliminary Development of a Complex Intervention for Osteopathic Management of Dysfunctional Breathing

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## ABSTRACT

### Background

Breathing retraining (BRT) is commonly used during osteopathic consultations as an adjunct to osteopathic manual therapy (OMT) for assessment and treatment of breathing-related dysfunction. Although BRT and OMT are widely recognised within osteopathy and other allied health disciplines, there are few descriptions of clinically applicable protocols in the literature.

### Objective

To describe the development of a dual-protocol framework (BRT and OMT) for assessment and treatment of dysfunctional breathing.

### Design

Development and evaluation of a complex intervention.

### Methods

Cyclical, iterative processes of development, feasibility and piloting, evaluation and subsequent redevelopment were applied in the design of two conceptual protocols for BRT and OMT.

### Results

The resulting BRT protocol consists of progressive steps of breathing practice in three body positions (neutral, flexion, extension), followed by a guide for more advanced breathing challenges that can be tailored towards the individual. The OMT protocol provides a semi-standardised assessment and treatment plan, which details body regions for assessment of somatic dysfunction and a list of techniques that can be selected according to practitioner clinical judgement, based on patient presentation and preferences, and clinical context.

### Conclusions

Here we present a clinically applicable guide for a complex intervention entailing assessment and management of dysfunctional or abnormal breathing. Implementation of this protocol within the clinical setting is now recommended, along with ongoing development, and further randomised clinical trials assessing its efficacy, effectiveness, and acceptability.

**Key Words:** Abnormal Breathing Pattern Disorders, Breathing Dysfunction, Breathing Exercises, Physical Therapy Techniques, Osteopathic Manipulation

## INTRODUCTION

Dysfunctional breathing (DB) is an alteration in the normal patterns of breathing and results in intermittent or chronic symptoms mediated through biomechanical, biochemical and psychological mechanisms.[1] Multifactorial, diffuse, but cumulative pathological and pathophysiological changes make DB difficult to diagnose, and a diagnosis of DB is often arrived at by exclusion.[2] DB may present with diverse symptoms and signs including respiratory, cardiac, neurological, metabolic and gastrointestinal presentations.[3] Many of these symptoms arise from respiratory alkalosis brought about by chronic or transient bouts of hyperventilation and the term 'hyperventilation syndrome' has often been used to describe this state.[4] However, it is now accepted that the clinical picture of DB encompasses more than traditionally recognised hyperventilation syndrome, since experimentally provoked hyperventilation will not consistently elicit symptoms, and symptoms may appear in the absence of decreased end-tidal pCO<sub>2</sub>. [5, 6] Furthermore, distinctions have recently been made between thoracic (involving ventilatory alterations), and extra-thoracic (e.g. vocal cord dysfunction) forms of DB.[3, 7]

Symptoms arising from DB may occur independently of other medical conditions or secondary to them.[4, 8, 9] DB is also strongly associated with anxiety and affective states.[10] To date there has been no attempt to establish a consensus on diagnostic criteria for DB. For this reason, and because most evidence associating DB with other medical conditions is cross-sectional, it is difficult to establish whether conditions may cause or exacerbate DB or, conversely, when symptoms arising from DB exacerbate the existing condition.

Various interventions have been developed to address DB.[11, 12] These can be broadly classified into two groups: (i) those that focus on improving conscious neuromuscular control of ventilation, commonly referred to as 'breathing retraining' (BRT); and (ii) those that apply manual therapy to improve the mechanical function of body structures involved in breathing.

Courtney and Greenwood,[13] and more recently Chaitow,[14, 15] have outlined principles of osteopathic assessment and management of DB. Despite this, there are few clear descriptions of a practical osteopathic approach to DB in the literature. We propose that a comprehensive approach should encompass both BRT and osteopathic manual therapy (OMT). The aims of BRT are to aid neuromuscular reacquisition of normal breathing patterns and to utilise and reinforce alterations in respiratory function facilitated by OMT. OMT, or particular manual therapy techniques, may have a role in improving breathing mechanics, in those with chronic conditions [16-19] or in healthy individuals [20], by mitigating biomechanical or somatic dysfunction that interferes with motor skill training in the form of BRT. Thus, BRT and OMT may be co-dependent within an intervention.

Complex interventions comprise multiple interacting features, those arising from the intervention itself, as well as from a diversity of behavioural characteristics of both patients and practitioners.[21] Craig *et al.*, 2008 have described a process of development, feasibility and piloting, evaluation, and implementation as key elements in the design of complex interventions.[21] Here we describe iterative cycles of these elements employed in the initial development and preliminary evaluation of two protocols for an individualised approach to osteopathic management of DB, incorporating both BRT and OMT.

## METHODS

### Development Phases

Key processes for development of BRT and OMT protocols were adapted from Craig *et al.*'s 2008 model for developing and evaluating complex interventions.[21] Craig *et al.* argue that in practice, the four elements of their model (Development, Feasibility and Piloting, Evaluation, and Implementation) may not occur in a linear or even cyclical sequence. Here, we describe three iterative cycles of Development, Feasibility and Piloting, and Evaluation leading to the development of a complex intervention ready for Implementation (Figure 1). Intermediate protocols were delivered in a randomised-controlled clinical trial investigating the effect of BRT and OMT on DB symptoms, cardiac autonomic measures and exercise economy (Clinical Trial Registration: ACTRN12613001267741; Research Ethics Approval: UREC 2013-1080).

### First Iteration: Concept 1

The first stage of development entailed identification of the evidence base for breathing interventions, underlying theory surrounding mechanisms and current clinical ideas and practice. A literature review was undertaken and a 3-hour symposium was organised by the authors (Symposium I), at which clinicians with a special interest and expertise in DB were invited to deliver a talk on evidence and experience surrounding recognition, assessment and management of the condition specific to their differing fields of practice. Symposium I concluded with a discussion about the common features of optimal management of the patient experiencing DB symptoms. Included in this discussion were suggestions about the likely clinical aims of OMT as well as of body positions that would provide sufficient challenge for practice of diaphragmatic breathing. Thus, protocols for an integrated intervention which included plans for OMT plus specific BRT were developed from this symposium (Concept 1). The BRT protocol was designed to allow home-based practice for the purpose of improving habitual breathing patterns. It was supported by online and printed materials and guidelines for regular assessment of progress. The OMT protocol was a goal-oriented semi-standardised osteopathic assessment and treatment plan for somatic dysfunction associated with breathing dysfunction. Feasibility testing and piloting of Concept 1 involved a series of informal workshops at

which the concepts were presented to postgraduate level osteopathy students and clinical tutors, who applied the suggested approaches on each other and provided feedback.

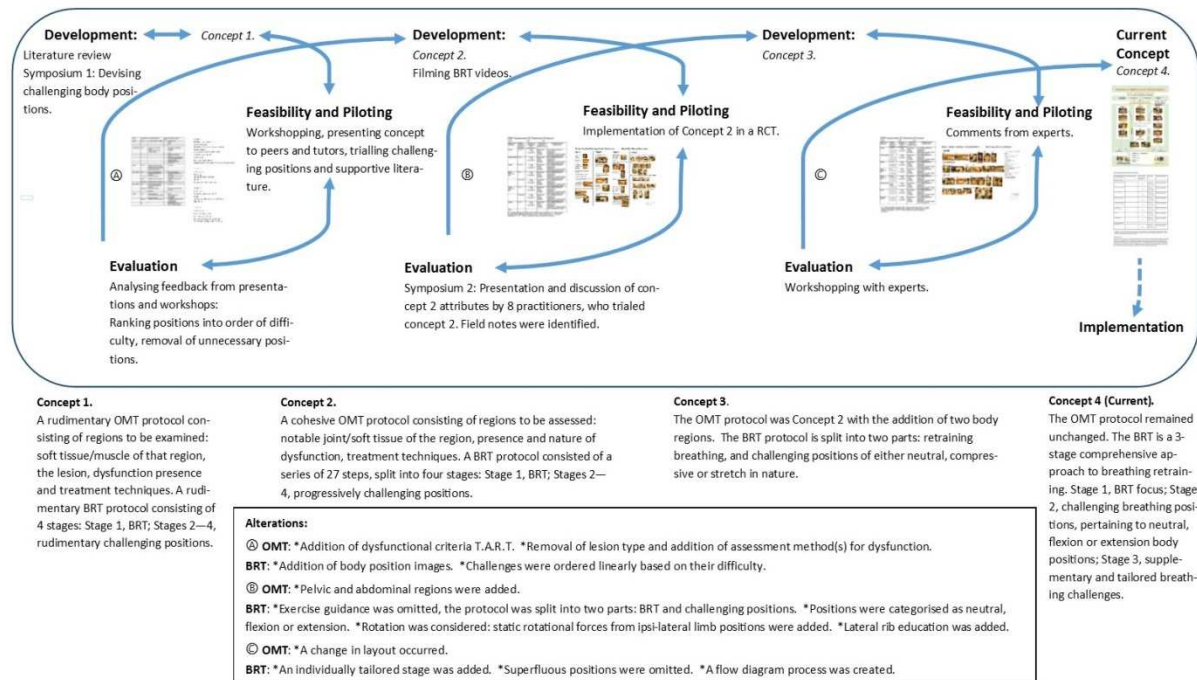


Figure 1. Development and Evaluation of a Complex Intervention for Dysfunctional Breathing. Abbreviations are as follows: BRT, breathing retraining; OMT, osteopathic manual therapy; RCT, randomised controlled trial; TART, texture, asymmetry, range of motion, and tenderness.

## Second Iteration: Concept 2 (Clinical Trial) Protocols

Feedback from the informal workshops was analysed, both protocols were revised to develop Concept 2 which was then utilised as the intervention in the clinical trial.[22] For the BRT, the order of exercises was adapted to facilitate gradual progression; and for OMT, simplified guidelines for assessment of somatic dysfunction were added. Eight osteopath clinicians, who expressed an interest in being involved in this area of research, evaluated the intervention while treating healthy active ( $\geq 4$  hours exercise/week) 19 – 45 year old participants who perceived that breathing might be limiting their exercise performance, recruited as part of the clinical trial. Clinicians included both clinical teaching staff ( $n = 3$ ), and private practitioners ( $n = 5$ ). All except one of these clinicians attended Symposium I, and all were invited to participate in a second 3-hour symposium (Symposium II), scheduled 9 months after the first. Five of the clinicians prepared a presentation for Symposium II, and the remaining three provided written or verbal feedback to authors, for which they were instructed to critique the Concept 2 protocols used within the study and during their routine clinical practice. They were asked to consider practical utility, and aspects requiring development and modification. In

order to synthesise information coming from these critiques, two investigators (JB and CB) independently produced field notes from the feedback provided.

### Third Iteration: Concept 3

On the basis of the evaluative process of Concept 2 protocols following Symposium II, the development team made modifications to the protocols which were then documented as Concept 3. Several key changes were made to the BRT and OMT protocols. The BRT protocol was rearranged into 3 stages from the original 27 steps, several body positions were removed and more emphasis was placed on 'lateral rib breathing'. The OMT protocol received two further specifically-identified regions for assessment of somatic dysfunction: the pelvis and abdominal wall regions. Concept 3 protocols were distributed to practitioners and amongst the research group for comment. Further minor refinement took place following informal presentation and discussion with field experts at a national osteopathic conference, resulting in the development of Concept 4 protocols presented here. The OMT protocol was unaltered between Concepts 3 and 4. Most of the changes within the second and third iterations therefore occurred in the adaptation of the BRT protocol. The key changes made at each stage of concept development are summarised at the foot of Figure 1.

## RESULTS

### Concept 4: Breathing Retraining (BRT) Protocol

The resulting Concept 4 BRT protocol is arranged in three stages. Stage 1 focusses on developing components of supposed optimal breathing (Figure 2). Stage 2 consists of three routines which each progressively introduce a series of challenging breathing positions emphasising neutral, flexed or extended body positions. The order of the flexion and extension routines is interchangeable, with the position providing the lesser challenge to the performer implemented first (Figure 3). Stage 3 comprises a guide to individually-tailored functional breathing challenges and static supplementary breathing challenges (Figure 3). Practitioner and patient self-assessment of breathing quality for each step in the progression was an integral part of the protocol. Assessments were made of whether breathing was appropriately nasal and abdominal, exhalation was longer in duration than inhalation with an appropriate following pause, had consistent rhythm, and had appropriate rate and sounds. Progress was recorded on a simple breathing assessment form (not shown).

## STAGE 1 BREATHING RETRAINING PROGRESSION

**Step 1: Nasal passage awareness**

Feel the air flow in through the nose into the back of the throat. Feel the warm air coming out through the nasal passage and over the lip. This can be aided by pursing the upper lip or placing a finger on top of the lip. Maintain awareness of breathing; keep thinking about the air flowing through your nose.

**Step 2: Hi-Lo awareness**

Place one hand on your chest the other over your abdomen (in between your ribs and navel), feel which hand rises the most.

**Step 3: Nasal breathing with abdominal movement**

The aim here is to breathe through your nose, ensure your abdomen rises during your in breath and falls during your out breath. Your upper chest should stay motionless. Feel your lower ribs move out to the side as well as to the front and back. Awareness of motion can be aided by using a towel or belt wrapped around the abdomen, or by placing a weight upon the abdomen or chest. Blow a balloon up 1/4 full, keep it in your mouth as seen on the video. If you use your mouth to breathe, the balloon will change in size, ensure this does not occur.

**Step 4: 'Out' breath longer than in breath.**

The length of your out breath should be equal to, or longer than your in breath. Comfortably alter your breath, stay relaxed, changing it when ready.

**Step 5: Pause after out breath**

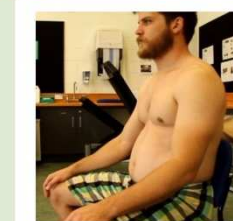
After the end of each out breath pause for a second, then inhale.

**Step 6: Evenness of breath**

Ensure that each breath is as deep/shallow as all the previous and the duration of breaths are the same.

**Step 7: Steps C, D, E and F. (Nasal, Out, Pause, Evenness = "N.O.P.E")**

Note that the Steps 3 to 6 are the characteristics features of a 'good breath'. To help make this memorable we use the acronym "N.O.P.E", where N = Nasal breathing, O = Out longer than in, P = pause at end of our breath, E = evenness of breath. Give it a go.

**Step 8: N.O.P.E while lying on your back with your knees bent.****Step 9: N.O.P.E while lying on your back, legs straight.****Step 10: N.O.P.E while seated.**

Nasal  
Out  
Pause  
Evenness

Stage 1 Breathing Retraining Quick Reference  
Version 2.1

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Figure 2: Concept 4 Breathing Retraining Protocol, Stage 1.

Stage 1 of breathing retraining (BRT) protocol, consisting of 10 challenge steps. Breathing awareness is developed (Steps 1 & 2); a series of independent breathing patterns are taught (Steps 3 – 6); then combined (Step 7). Finally, the combined breathing pattern is maintained during seated and supine body positions (Steps 8 – 10).

# BREATHING RETRAINING PROGRESSION

## STAGE 1 (BREATHING RETRAINING)

Nasal Out Pause Evenness (N.O.P.E) Breathing *(See Stage 1 chart for further instructions and positions).*

N = Nasal breathe in and out of your abdomen and lower rib cage.

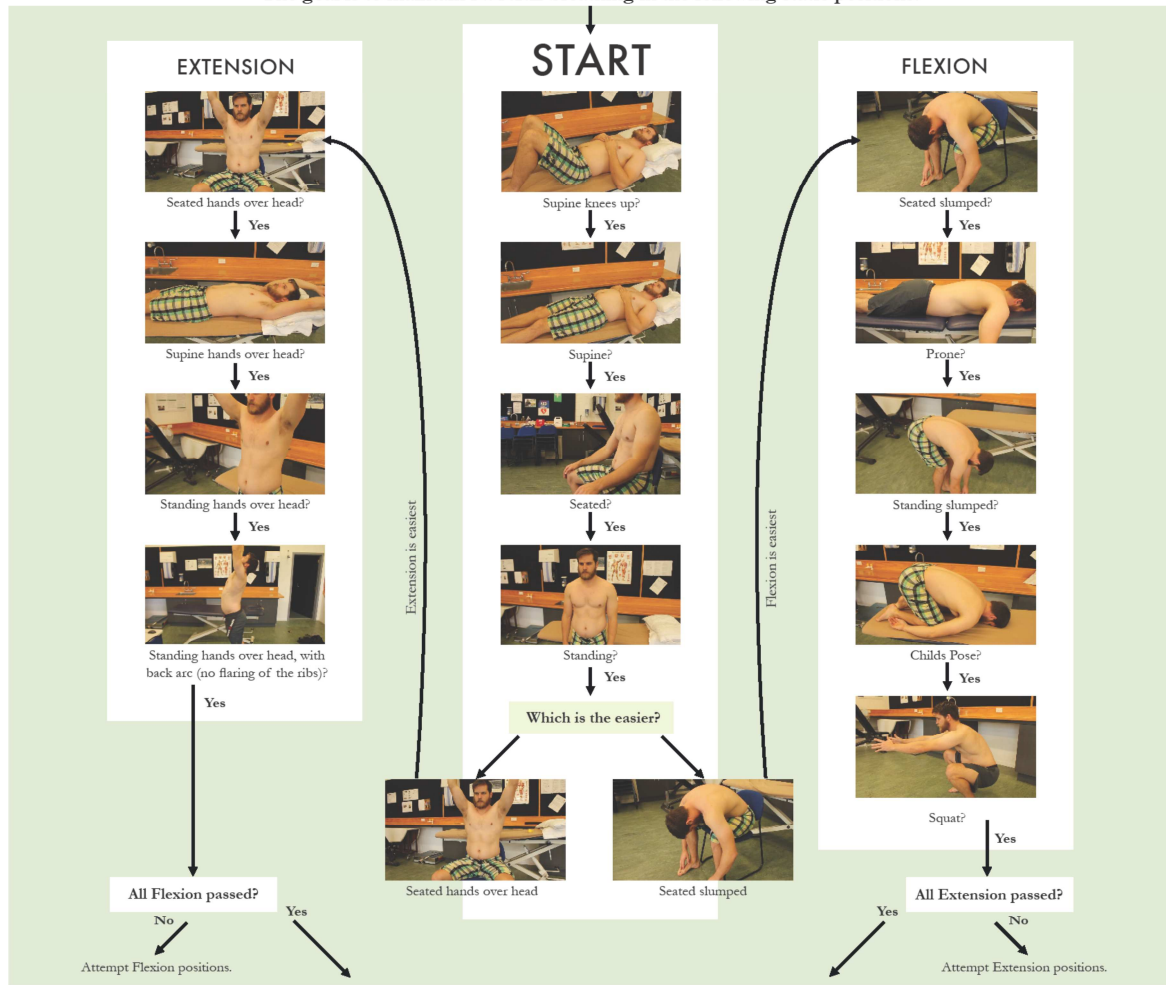
O = Out breath is longer than in breath.

P = Pause after out breath.

E = Evenness of breath duration and consistency.

## STAGE 2 (PROGRESSION)

The goal is to maintain N.O.P.E breathing in the following static positions.



## STAGE 3 (TAILORED CHALLENGES)

Functional movements : Walking, Walking hands over head, Walking with weight.

Supplementary static positions:



During any given task, activity, position or stressor, attempt to maintain N.O.P.E breathing, increase the intensity and duration as required. You own an action if you can breathe in it.

Breathing Re-Training Quick Reference Version 3.1qJB  
Benjamin, J.G., Verhoeff, W.X., Moran, R.W., Bacon, C.J.

Figure 3: Concept 4 Breathing Retraining Protocol, All Stages.

The entire progression in the Concept 4 breathing retraining (BRT) protocol. Stage 1: Breathing retraining focus; Stage 2: Challenging breathing positions, pertaining to neutral, flexion or extension body positions; Stage 3: Supplementary and tailored breathing challenges.

Nasal, Out, Pause, Evenness (N.O.P.E.) acronym cues nasal breathing, exhalation longer than inhalation, pause following inhalation, and evenness of breath.

#### Concept 4: Osteopathic Manual Therapy (OMT) Protocol

The resulting Concept 4 OMT protocol was designed as a semi-standardised assessment and treatment approach, which provided a list of body regions most relevant to addressing somatic components of breathing dysfunction and a range of techniques selected according to practitioners' clinical judgements, based on patient presentation and preferences and clinical context (Table 1). An accompanying treatment worksheet and notation system was also developed (see supplementary online material).

Table 1. Osteopathic manual therapy assessment and treatment approach.

A. Physical examination and assessment to identify presence of somatic dysfunction in each of the following regions:	B. For each region in which somatic dysfunction is present, address by selecting, at the practitioner's clinical judgement, one or more of the following osteopathic techniques:
<i>Mandatory</i>	
1. Cervical spine (upper, and mid-cervical spine)	Soft-tissue techniques
2. Cervico-thoracic spine	Myofascial release
3. Thoracic spine	Positional release / strain-counterstrain
3a. Upper thoracic spine and ribs (ribs 1–2 ; sternoclavicular, acromioclavicular joints)	Functional technique Balanced ligamentous tension Muscle-energy techniques
3b. Lower thoracic spine and ribs (ribs 3–12; diaphragm)	High-velocity, low-amplitude manipulation
4. Lumbar spine (L1–S1; iliopsoas)	Joint mobilisation / articulation
5. Pelvis	Mobilisation with movement
6. Abdominal wall	
<i>Discretionary</i>	
1. Other region/s	

Notes: L = lumbar vertebrae; S = sacral vertebrae.

## DISCUSSION

This report describes the preliminary development of a treatment and management approach that could be practically implemented with individuals who exhibit signs or symptoms of DB. The development of this integrated BRT and OMT approach was undertaken with the collaboration of practicing osteopaths and other clinicians with expertise in breathing dysfunction. Clinician feedback on the concept protocols was reflective and diverse and occurred at several stages, enabling consideration of their use in a wide range of contexts and adaptations which are likely to improve general clinical applicability.

Several ideas that arose from evaluation within the three development cycles warrant discussion. Firstly, various collateral benefits of following the BRT protocol have been identified. Secondly, though feedback from practitioners indicated acceptable face validity and applicability within routine clinical settings, the applicability of the BRT to the clinical situation was the focus of critical reflection at all stages of the evaluation process. Reflection occurred particularly in relation to session duration and number of challenge steps in the protocol. The possibility that some steps in the BRT protocol might be redundant in most clinical situations was considered.

For the OMT protocol, evaluation has centred on its purpose and use amongst practitioners with a diverse range of practice styles. Further discussion pertaining to both protocols and their integration includes the implications of assessing the Concept 2 (Clinical Trial) protocols on healthy active individuals and the length of time required to complete the protocols in relation to a typical osteopathic consultation.

### Collateral Benefits of the BRT Protocol

An unanticipated outcome for use of the protocol was that previously unidentified dysfunction became apparent to practitioners in the course of delivering the BRT. Using the protocol sometimes uncovered musculoskeletal dysfunctions such as impaired range of movement or motor patterns, for example an inability to lateral rib breathe was highlighted in flexion positions. Sometimes dysfunctions unrelated to the main purpose of the test were highlighted when individuals failed to assume positions, for example poor ankle dorsiflexion was identified during a failed squat attempt. Alternatively, musculoskeletal dysfunction noted in body regions indirectly associated with breathing function were reported to affect breathing in certain body positions, such as a propensity to upper rib breathe during ipsilateral glenohumeral external rotation, with shoulder joint dysfunction.

Another indirect benefit of BRT implementation noted in the evaluation process was an observed improvement of breathing and whole body awareness that sometimes developed simultaneously with its use. Improved awareness of body functions, termed 'interoception', [23] could possibly increase the ease of acquisition of the BRT challenges, however this needs to be further investigated.

### Applicability of the Protocols to the Clinical Situation

The length of time required to integrate these protocols may exceed the duration of routine osteopathic consultation in usual practice. In relation to the BRT protocol, evaluators made a number of suggestions about how the process could be adapted to address this. For example, some clinicians reported 'cherry-picking' challenging positions applicable to their patient and testing-retesting the patients only on these challenges. Furthermore, some clinicians, particularly in the evaluation of the Concept 2 protocol, considered some steps to be redundant in most clinical situations, and that shortening and simplifying the protocol might improve its applicability.

We have attempted to incorporate modern principles of motor skill development within the BRT protocol. A current model for developing a well-learned, resilient motor pattern is to allow exploration and practice of the best movement solution within a range of practice conditions. Schöllhorn *et al.* argue for the importance of applying variations in kinematic and kinetic properties of movement in its acquisition to stabilise learning.[24] These authors demonstrate 94% greater improvement in a group of young hurdlers randomly assigned to a 6-week training programme incorporating variability in body positions and practice tasks. The programme was oriented towards developing individual and situational movement solutions in hurdling, compared to a more traditional practice towards mastery of traditional drills displaying increasing similarity to the supposed optimal movement technique.[24] Therefore in the final BRT protocol, additional scope for adapting breathing in a greater variety of situations has been provided. If respiratory mobility is increased by OMT, then the range of possible movements (degrees of freedom) allowed in these situations would also have increased, perhaps providing further variety for developing breathing motor control that was more responsive to changing conditions. We recommend application of as many steps as can reasonably be achieved within the available time-frame without compromising quality.

A final issue of applicability was that practitioners found it difficult to observe breathing in positions where movement or body parts obstructed observation. For example, during seated slumped when the anterior chest view is obstructed. The suggestion was made to assess such cases with the aid of palpation.

### Purpose and Application of OMT Protocol

The differing practice styles apparent amongst osteopaths make it difficult to develop a semi-standardised assessment and treatment that is universally applicable. The evaluation process revealed that different clinicians used the OMT protocol in slightly different ways. Some clinicians found that using the protocol markedly changed their normal practice routine.

The OMT protocol was designed as a semi-standardised guide for treatment for the purposes of describing a research intervention. It was intentionally designed to accommodate a range of practitioner preferences in administering examination and treatment techniques, whilst setting some

constraints. It was not intended to provide a prescription, nor to represent or replace clinical reasoning and practitioner judgement in determining the most appropriate form of OMT applied. An effort was made to balance between detailed explanations of assessment or treatment and abbreviated reporting, which may have incurred a degree of generalisation not suiting all practitioners' approaches to practice.

During evaluation of the Concept 2 protocol it was highlighted that the OMT protocol lacked hierarchy surrounding the severity of the dysfunction(s) presented. This meant some practitioners were sometimes unsure on an order of treatment priority for an individual's dysfunctions. An attempt was made for subsequent protocols to provide greater clarity of the intention that the semi-standardised plan was not to specifically direct treatment but to provide a framework that encouraged individual practitioner judgement on the basis of the practitioner's own clinical reasoning in each case.

Some practitioners also noted that following the protocol resulted in a substantial change from their usual treatment approach. A sense of compromising 'flow' during consultation was sometimes noticed, and this may reflect the need for further development around operationalising the protocol in practice. Whilst some practitioners tended to deviate from their regular treatment in order to accommodate the semi-standardised approach, others maintained their regular approach, which they attempted to retrospectively fit into the model presented. Practitioners reported that they found this tool effective as an assessment chart and acknowledged that the protocol may be useful as a 'checklist' for novice and trainee osteopaths.

### Limitations of Testing the Protocol on Healthy Active Individuals

During evaluation of the Concept 2 (Clinical Trial) protocols, clinicians noted that involving relatively healthy patients may have limited the degree to which the protocol could be applied in other clinical settings. Practitioners pointed out that patients' pre-existing conditions or health status could affect the management and the progress of using the intervention. Sometimes these specific conditions tended to direct treatment planning, rather than the breathing itself. At other times, breathing issues would not resolve until a dysfunction located outside of respiratory structures was addressed, suggesting that even peripheral dysfunctions, such as a sprained ankle, may affect breathing function and health.

Secondly, the patterns of dysfunction highlighted in the evaluation of the Concept 2 BRT protocols may have been specific to the activities undertaken by patients. The patients in this evaluation were mainly well-trained individuals, with many reporting regular participation in endurance or resistance training or sport-related conditioning. As such, their levels of strength, fitness, flexibility and motor pattern adaptability may have been greater than more typical clinical populations. Implementing this

protocol on a different population may present different challenges associated with greater difficulty in achieving the more advanced breathing challenges.

Thirdly, practitioners pointed out that compliance would be an important factor for the successful implementation of the BRT protocol. The physically active patients who volunteered to take part in the trial for which this intervention was developed were mainly sportspeople, and were possibly more highly motivated to improve their breathing than many clinically-treated DB patients. Therefore, we consider that this group may have displayed a greater level of compliance than is typical within the clinical setting. Attaining motivation and compliance might have been difficult for steps that provided greater challenge to the individual. It was felt that these could be addressed through practitioner-designed, patient-specific interim challenges.

Exercise is associated with relative protection from a range of psychological health disorders.[25] It is therefore also possible that active participants might respond more favourably to the intervention. We recognise that neither protocol may be effective without consideration of psychosocial elements that often underpin or are closely linked to disturbed breathing patterns.[26, 27] BRT may also have a role in the treatment of anxiety and depression.[28] There are multiple components of DB, and the protocols developed here focus primarily on two: motor skills and somatic dysfunctions likely to be associated with breathing, but at present the described protocols do not specifically address psychosocial issues that may be important determinants of dysfunctional breathing.

### Suggestions for Further Research

This investigation does not extend to a true implementation phase of a complex intervention. A report on the efficacy of the developing protocols is necessary, and an investigation of implementation in a broader clinical setting would be the next logical step. Implementation is envisaged by Craig *et al.* as including dissemination, ongoing surveillance and monitoring and longer-term follow-up.[21] We argue that evaluation of a complex intervention should be a continuous process, maintained through feedback following implementation, as well as from subsequent research. Further, we suggest that clinical and physiological outcomes of using this protocol should next be assessed in rigorously-designed clinical trials.

Input from patients regarding their experiences might have been more strongly emphasised during the different iterations of the development process, and should be applied in future research. There is also potential for further exploration of specific instructions or non-verbal cues as feedback, for example using a rolled towel under the thorax to mobilise breathing structures, or promotion of breathing awareness through inflating a balloon. Although such cues were applied in the BRT protocols during development, they could be extended. Further work might alternatively focus on development of BRT in stressful situations or as an intervention for breathing-mediated anxiety.

## Conclusions

The literature on DB provides a comprehensive theoretical basis for understanding an approach to treatment but does not provide practical guidelines. This report describes the development and evaluation of a novel dual-protocol framework for clinical assessment, diagnosis and management of DB. Further research to investigate the efficacy of the protocols within a clinical setting is recommended, along with ongoing development.

## Author Contribution Statement

JB, CB and RM developed the initial idea for and design of the study. JB and CB co-ordinated the study data collection and analysis. JB, WV and RM developed the protocols. All authors contributed to data analysis and interpretation. JB and CB drafted the initial manuscript and WV and RM contributed to later versions. All authors read and approved the final version of the manuscript.

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For assistance with data collection

## Competing Interests

RM is an executive editor of the International Journal of Osteopathic Medicine but was not involved in review or editorial decisions.

There are no other conflicts of interest.

## What This Paper Adds

- A novel, clinically-applicable osteopathic approach to dysfunctional breathing is described
- The cyclical process of development, piloting and evaluation of the complex intervention presents a valuable model for designing osteopathic interventions
- The intervention was developed in consultation with a large number of clinicians and experts in the field
- Implementation and further randomised clinical trials assessing its efficacy, effectiveness and acceptability are recommended

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JB, CB and RM developed the initial idea for and design of the study. JB and CB coordinated the study data collection and analysis. JB, WV and RM developed the protocols. All authors contributed to data analysis and interpretation. JB and CB drafted the initial manuscript and WV and RM contributed to later versions. All authors read and approved the final version of the manuscript.

**Ethical statement**

Ethical approval was obtained from the Unitec Research Ethics Committee (Approval No.: UREC 2013-1080) and all participants gave written informed consent to participate. The study was registered with the Australia New Zealand Clinical Trials Registry (ACTRN12613001267741).

**What this paper adds**

- A novel, clinically-applicable osteopathic approach to dysfunctional breathing is described
- The cyclical process of development, piloting and evaluation of the complex intervention presents a valuable model for designing osteopathic interventions
- The intervention was developed in consultation with a large number of clinicians and experts in the field
- Implementation and further randomised clinical trials assessing its efficacy, effectiveness and acceptability are recommended