

Before-after study to determine the effectiveness of an adjustable wood frame-foam and wool mattress bed-system (The Natura Mattress System) in reducing chronic back pain in adults

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Objective and Design: The purpose of this 6-week Before-After trial was to investigate the effectiveness of the Natura Mattress System in reducing back pain by ≥ 1 unit on the 11-Point Pain Severity Scale ($p \leq 0.05$), in chronic low back pain sufferers.

Subject Profile: The subjects were adults recruited from within and outside the Canadian Memorial Chiropractic College (CMCC) Outpatient Clinic, with chronic low back pain (LBP) of ≥ 2 months duration at the time of entering the study.

Sample Size: 15 subjects were targeted to complete the study.

Outcome Measures: The primary outcome measure consisted of: morning severity of pain as measured by an 11-point ordinal pain scale (Numeric Rating Scale or NRS). Secondary outcome measures consisted of: (1) daily quality of sleep as measured by a 4-point ordinal scale; (2) effect on daily activity as measured by a 4-point ordinal scale; and (3) daily quantity of analgesics. These outcomes were collected via a daily diary-type of questionnaire.

Statistical Analysis: Baseline to 4-week post treatment-commencement differences were analyzed for statistical significance using Repeated Measures ANOVA, at the 0.05 level of significance. In addition, all outcome measures were graphed and examined descriptively for any clinically important changes across the 6 week time-frame of the study.

Methods Protocol: Eligible subjects who read and signed the written informed consent form, were given a package containing a copy of the written informed consent form, and upon completing the 2 week baseline

Objectifs et méthodologies : le but de cet étude avant-après d'une durée de 6 semaines était de vérifier l'efficacité du système de matelas Natura dans la réduction des maux de dos atteignant 1 point ou plus sur l'échelle de 11 points de gravité de la douleur ($p \leq 0.05$) chez les personnes souffrant de lombalgie chronique.

Profil des sujets : les sujets étaient des adultes recrutés à l'intérieur et à l'extérieur de la clinique de consultation externe du Canadian Memorial Chiropractic College (CMCC), souffrant de lombalgie chronique depuis 2 mois ou plus au moment de leur inscription à l'étude.

Mesures des résultats : la mesure principale du résultat était la suivante : la gravité de la douleur matinale mesurée par une échelle ordinaire de douleur de 11 points (échelle d'évaluation numérique). Les mesures secondaires des résultats comprenaient : (1) la qualité quotidienne du sommeil mesurée par une échelle ordinaire de 4 points ; (2) l'effet sur l'activité quotidienne mesuré par une échelle ordinaire de 4 points ; et la quantité quotidienne d'analgésiques. Ces résultats ont été recueillis tous les jours sur un agenda-questionnaire.

Analyse statistique : les différences entre les données d'origine et les données obtenues 4 semaines après le début du traitement, ont été analysées afin de déterminer une signification statistique grâce à l'analyse de la variance par mesures répétées, à un niveau de signification de 0,05. En outre, toutes les mesures des résultats ont été transposées sur des graphiques et examinées de façon descriptive pour déceler tout changement clinique important sur les six semaines de l'étude.

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daily diary questionnaires, were contacted by the bed manufacturer, who arranged with the subject a date and time of mutual convenience to deliver the bed (twin or queen size). The subject was then required to complete 4 more weeks of diary questionnaires. Thank-you cards were sent to each subject who completed the study.

Results: The sample consisted of 6 caucasian females and 7 caucasian males, between the ages of 22 and 75 years, with an average(sd) age of 37.0 (18.44) years. Five subjects were adult students, 5 had sedentary occupations, while 3 had relatively physical occupations. Baseline low back pain (LBP) severities of the sample ranged from 2 to 8 on the 11 point pain scale (NRS), with an average(sd) level of 3.0 (1.75). Average duration of the subjects' chronic LBP state was 5.6 years, ranging from 3 months to 30 years. Only 2 subjects were taking LBP medications at the start of the study.

Conclusion: For a generally well educated, young (20-40 years of age), caucasian population with mild-moderate chronic LBP, use of the Natura Bed can be expected to result in a clinically important reduction in pain severity upon both waking and at the end of the day, of at least 1 point (on the NRS) over a 4 week period ($p \leq 0.05$).

Further research is recommended which utilizes the Randomized Clinical Trial (RCT) design to investigate the performance of the Natura Bed compared to other beds on the market, and assesses patient characteristics predicting suitability for the Natura Bed. (JCCA 1997; 41(1):16-26)

Protocole des méthodes : les sujets admissibles qui ont lu et signé la formule de consentement éclairée, ont reçu un paquet contenant une copie de la formule de consentement éclairé. Après avoir complété les questionnaires pendant les deux premières semaines, ils ont été contacté par le fabricant de lit qui a fixé avec eux une date et une heure de livraison (lit à une place ou grand lit à deux places). Le sujet a ensuite continué à remplir les questionnaires quotidiens pendant quatre semaines supplémentaires. Des cartes de remerciements ont été envoyées à toutes les personnes qui ont pris part à l'étude.

Résultats : l'échantillon était composé de 6 femmes et 7 hommes de race blanche, âgés de 22 à 75 ans, avec un âge moyen de 37 (18.44) ans.

Cinq sujets étaient des étudiants adultes, 5 avaient des occupations sédentaires, tandis que 3 avaient relativement peu d'activités physiques.

Les données de départ sur la gravité de la lombalgie variaient de 2 à 8 sur une échelle de douleur de 11 points avec un niveau moyen de 3 (1,75). La durée moyenne de la lombalgie chronique était de 5,6 ans, allant de 3 mois à 30 ans. Deux sujets uniquement prenaient des médicaments contre la lombalgie chronique au début de l'étude.

Conclusion : pour une population jeune (20 à 40 ans), de race blanche, globalement bien instruite, souffrant de lombalgie chronique légère à modérée, l'utilisation du lit Natura se traduit par une réduction importante, sur la plan clinique, de la gravité de la douleur, au réveil et à la fin de la journée, d'au moins 1 point (sur l'échelle d'évaluation numérique), sur une période de 4 semaines ($p \leq 0,05$).

On recommande d'approfondir les recherches utilisant le modèle d'essai clinique aléatoire pour comparer la performance du lit Natura à celle des autres marques disponibles sur le marché. On conseille également d'évaluer les caractéristiques du patient qui permettent de prédire que ce dernier bénéficiera de l'utilisation d'un lit Natura.

(JCCA 1997; 41(1):16-26)

KEY WORDS: sleep, bed, foam mattress, back pain, clinical trial.

MOTS CLÉS : sommeil, lit, matelas en mousse, maux de dos, essai clinique.

Introduction

The potentially therapeutic role of "the bed" in the management of back pain is generally acknowledged by most health care practitioners; in fact, bed rest still is a central component of conservative management of back pain in mainstream medicine.¹ It is well known too, that sleep deprivation, whether due to pain and discomfort while lying in bed, or other reasons, results in a lack of productivity and other disorders.⁶⁻¹¹ It is important, therefore, that back pain management strategies give due consideration to the patient's bed design.

Since sleep is such an integral part of overall well-being, it may not be surprising that several mattress and bed designs are available on the market; therefore it is perhaps surprising, that there is very little good quality, English-language, published evidence available supporting these products.

One study, wherein a "Canadian chiropractic research team" examined comfort levels for five kinds of mattresses (foam, futon, spring, water, air), on different body sizes, received a cursory description in a 1989 issue of the *Oklahoma Chiropractic Journal*.² While the foam and air mattresses were judged by the investigators to be superior to the other 3 mattresses tested, the descriptions and terms used in the article were too vague to enable drawing any conclusions about the quality of the study. The full paper in the English-language was not revealed in our searches of the literature on the Medline, Index to Chiropractic Literature, or ChiroLars databases.

From a 1987 survey³ based on the responses of 50 of the author's own patients who were documented waterbed users in 1984, the author concluded that "A majority of patients derive benefit from their waterbeds for upper and middle back pain stiffness. Fifty percent derive benefit for low back pain." The paper, however, is fraught with reporting and methodological problems, and is essentially not much more useful than anecdotal evidence. Specifically, since respondents were self-assigned to waterbed use, the results are biased towards people who are attitudinally predisposed towards waterbeds. The paper neither discloses what proportion of the clinic's waterbed users the 50 respondents are, nor what proportion of all those waterbed users who were solicited to complete the survey, the 50 respondents are, so that it is impossible to assess either the sample compliance rate, and ultimately, the sample profile representativeness. While the paper

provided percentages for positive and negative responses for effects on leg cramps, cold feet, back stiffness and back pain, it was not disclosed how many subjects comprised each of these complaint categories; so, for example, if there were only 2 subjects in the leg-cramp category, and the paper stated that 100% of leg-cramp sufferers experienced relief, then it would be evident that this complaint category is very poorly represented, and the results generated from it have extremely limited usefulness.

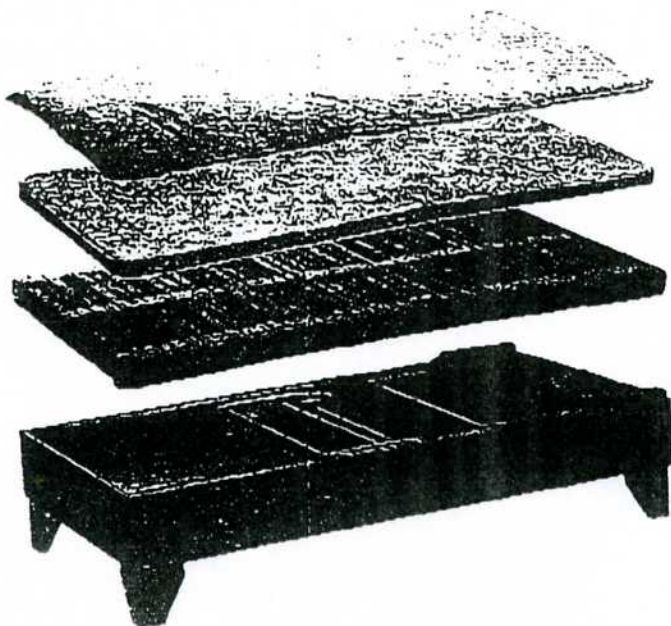
Our literature search revealed only one relevant Randomized Clinical Trial (RCT). In this study, Scriver et al.⁵ found that a combined customized exercise and alternating-air-mattress regimen was more effective in reducing back pain than either the exercise regimen or the alternating-air-mattress alone, in patients having recently undergone percutaneous transluminal coronary angioplasty (PTCA).

While the study appears to have merit for the PTCA backpain population, it is not clear that these results are generalizable to any other low back pain population; in addition, it is not possible to determine from this study how the alternating-air-mattress compares against any other type of mattress or bed-system, in reducing back pain.

Somewhat more relevant, is the Before-After-Crossover study by Garfin and Pye.¹ The authors concluded from the results of 15 chronic low back pain subjects, that "hard beds" are more effective in reducing back pain and improving straight leg-raising than "soft beds." The softer beds even appeared to exacerbate most subjects' back pain. Unfortunately, the study did not provide any data quantifying the extent of these pain reductions/increases, so that it is difficult to judge whether these changes are clinically significant; in addition, it appears that statistical significance was not achieved, so that this study's findings, while somewhat useful in the absence of any stronger evidence, should be regarded with caution.

One type of bed system which is relatively inexpensive and simple to assemble and disassemble, is that manufactured by *Natura World Incorporated*. This bed system features an all-wood frame, a flexible wood slat mattress supporting a foam mattress, which in turn, is covered by a sheep-wool mattress pad; other characteristics of the bed are: a sheep-wool duvet and pillow with added neck support, a neck contour rise and lumbar support lever incor-

Figure 1



The Natura Bed System

From bottom to top: Adjustable all-wood frame, flexible wood slat mattress, foam mattress, sheep wool mattress pad.

porated into the frame, and adjustable elevations of the head/back-rest portion of the frame.

It should be noted that while there is at least some weak support in the literature favouring elevated bed-backrests for recovering coronary angiography patients,⁴ our search of the literature did not reveal even one study which tested the therapeutic effectiveness of this type of bed for LBP. It is therefore the purpose of this 6-week Before-After trial to investigate the effectiveness of the Natura Bed System in reducing back pain by ≥ 1 unit on the NRS ($p \leq 0.05$), in adult chronic low back pain sufferers. Chronic back pain sufferers were targeted for this study because: (a) they lend themselves more appropriately to the Before-After study design, and (b) this sector of back pain sufferers is the most likely to be interested in investigating in a therapeutic mattress or bed system.

Methods

Study Design: The design was that of a Before-After Study.

Subject Profile: The subjects were adults recruited from within and outside the Canadian Memorial Chiropractic College (CMCC) Outpatient Clinic, with chronic low back pain (LBP) of ≥ 2 months duration at the time of entering the study.

Sample Size: 15 subjects were required to achieve statistical power of 80% at the 5% level of significance for a clinically important improvement in LBP severity of 1 unit on the NRS (11 point pain scale).

Intervention: This bed system features an all-wood frame, a flexible wood slat mattress, support foam mattress, which in turn, is covered by a sheep-wool mattress pad; other characteristics of the system are: a sheep-wool duvet and pillow with added neck support, a neck contour rise and lumbar support lever incorporated into the frame, and adjustable elevations of the head/back-rest portion of the frame.

The subject was required to use the bed every day for 4 weeks, fill in the diary questionnaire (postcard format) on a daily basis, and upon completion of each 1-week pre-stamped and addressed diary postcard, drop the postcard into the mail. During the baseline and experimental periods, an assistant followed up each subject on a weekly basis by telephone, to ensure that each subject was progressing in a satisfactory manner.

After the 4 week experimental period, the Company picked the bed up at a date and time prearranged with the subject. Thank-you cards were subsequently sent to each subject.

In the event that the subject was not compliant, in that she/he stopped submitting the diary postcards in a timely fashion, stopped using the bed, or asked to be excused from the study, and no reconciliation could be arranged with the subject, the investigator notified the Company, which in turn was responsible for retrieving the bed.

Ethics: The protocol was approved by the CMCC Institutional Review Board (IRB), and each subject was required to sign an informed written consent form.

Outcome Measures: The primary outcome measures consisted of morning, noon, and evening severity of pain as measured by the NRS (an 11-point ordinal pain scale).