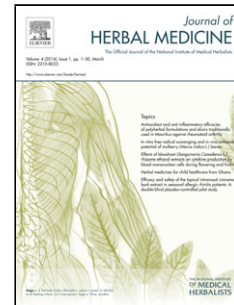


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Title

Characteristics of herbal medicine users among internal medicine patients: a cross-sectional analysis

Short title

Characteristics of herbal medicine users

Authors

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Highlights:

- Herbal medicine utilisation is common among chronically ill patients admitted to integrative inpatient care in Germany.

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- A large proportion of users indicated that herbal medicine was not helpful for their primary medical complaint requiring further investigations.

ABSTRACT

Background: Herbal medicine is among the most frequently used complementary medicines. This study aims to identify the socio-demographic and health-related predictors of herbal medicine utilisation among patients with chronic internal medicine conditions admitted to inpatient care.

Methods: Patients referred to a German integrative medicine clinic were asked whether they had ever used herbal medicine for their primary medical diagnosis, and whether they experienced benefits or harm. Socio-demographic characteristics, health behaviour, medical diagnosis, health status, mental health, satisfaction with health, and health locus of control were determined as potential predictors of herbal medicine use.

Results: Of 2,105 respondents, 41.9% reported herbal medicine use for their primary medical complaint, with 57.4% of them reporting perceived benefits and no harm due to use. Herbal medicine use was positively associated with female gender, at least high school education, a diagnosis of fibromyalgia, lung disease or sub-threshold depression, high internal health locus of control and avoidance of fast food, and was negatively associated with spinal pain. High satisfaction with life and high internal health locus of control were positively associated with perceiving herbal medicine as helpful. Whilst, being a smoker and diagnosed with headaches or irritable bowel syndrome had a negative association with the use of herbal medicine.

Conclusion: Herbal medicine utilisation among patients admitted to integrative inpatient care is common. While predictors of herbal medicine use appear to be in line with previous findings, there is a need for more in-depth examination of patients' motivations for the use of herbal medicine to further the understanding of their health behaviours and needs.

Abbreviations:

CAM - Complementary and Alternative Medicine

HADS - Hospital Anxiety and Depression Scale

FLZ - Fragebogen zur Lebenszufriedenheit (Satisfaction with life questionnaire)

ICD - International Classification of Diseases

GKÜ - Gesundheitsbezogene Kontrollüberzeugungen (Health locus of control)

SPSS - Statistical Package for Social Sciences

WHO - World Health Organisation

Keywords: Attitude; Chronic illness; Complementary medicine; Herbal medicine; Internal medicine; Utilisation

1. INTRODUCTION

Herbal medicine has long been used for the prevention and treatment of a wide range of medical conditions, as well as for general health enhancement (Wu et al., 2014; Zhang et al., 2008). In addition to broad indications of use, herbal medicine is also one of the most frequently used complementary medicines in Europe (Eardley et al., 2012; Frass et al., 2012), Singapore (Lim et al., 2005), Australia (Xue et al., 2007) and the US (Barnes et al., 2004; Clarke et al., 2015).

Previous studies have identified a number of factors associated with herbal medicine use including female gender, higher education, higher socioeconomic status and the presence of certain health conditions, such as menopausal symptoms and musculoskeletal disorders (Eardley et al., 2012; Frass et al., 2012). However, in Germany, very few studies have been undertaken that provide in-depth examination of the predictors of herbal medicine use, or the reasons why patients choose to use these medicines.

Understanding the determinants of herbal medicine use can generate important insights into the behaviours and needs of health consumers, which will be helpful in shaping and improving future policy, education, and practice and health service delivery. In recognizing the value of such research and addressing the significant research gap in this area, this paper reports the findings of a cross-sectional study examining the socio-demographic and health-related predictors of herbal medicine use among patients with chronic internal medicine conditions admitted to integrative inpatient care in Germany.

2. MATERIAL AND METHODS

2.1. Design

This descriptive cross-sectional survey formed part of an internal quality assurance program that evaluated the impact of integrative treatment on the health outcomes and quality of life of patients admitted to the Department of internal and integrative medicine - a clinical setting for patients with internal diseases, which applies both conventional and complementary therapies (Lauche et al., 2012) - at an acute-care, urban university hospital in Germany. While the department is likely to attract patients who are generally interested in integrative medicine, patients have to be referred to the department by their general practitioner. The costs of attending the integrative medicine clinic are covered by German statutory health insurance as well as many private health insurance

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companies and as such, treatment is not likely to be limited by personal treatment preference or socioeconomic class.

2.2. Participants

The study employed a convenience sampling technique whereby all patients referred to the Department of internal and integrative medicine between January 2001 and January 2004 were invited to participate. All patients were adults diagnosed with a chronic internal medical condition (Lauche et al., 2012), and had been referred to the department by a general practitioner for a two-week (minimum) period of inpatient treatment. The majority of patients referred to the hospital were severely affected by their disease conditions (Lauche et al., 2012), and had a history of unsuccessful treatments prior to admission. No other inclusion or exclusion criteria were applied.

2.3. Outcomes

The self-administered, pencil-and-paper based survey comprised 36 items, and had an estimated completion time of 30 minutes. The survey was designed to measure six core outcomes, each of which are defined below.

Herbal medicine use: The Freiburg Questionnaire on Attitudes on Naturopathy was administered to identify the range of complementary medicine used by participants to treat the primary medical complaint prior to receiving integrative inpatient treatment (Huber et al., 2004). For the analyses presented here, only herbal medicine use was evaluated, for which the following question was asked: *Have you ever used herbal medicine for your primary medical complaint?* (Response options: yes, no). Patients who reported the use of herbal medicine for the management of their primary medical complaint were also asked: *How helpful was herbal medicine for your primary medical complaint?* (Response options: helpful, not helpful, harmful).

Socio-demographic characteristics: Participant age and gender were sourced from hospital records. Additional socio-demographic information regarding level of education (i.e. less than high school, high school graduate), employment status (i.e. full-time, part-time, unemployed), and relationship status (i.e. in a relationship or not in a relationship) was collected via the survey. These variables served as possible predictors of herbal medicine use, together with the following health behaviours: smoking status (i.e. current smoker, past smoker, non-smoker), alcohol intake (i.e. abstainer, less than twice weekly, at least twice weekly), and fast food consumption (i.e. abstainer, less than twice weekly, at least twice weekly).

Health status and clinical characteristics: The patient's main diagnosis was ascertained by the referring doctor and recorded as an ICD-10 diagnosis code (World Health Organization). For this analyses, diagnoses were categorised as: a) osteoarthritis, b) arthritis, c) fibromyalgia, d) spinal pain, e) headache, f) other pain, g) hypertension, h) ischaemic cardiac disease, i) irritable bowel syndrome, j) inflammatory bowel disease, k) lung disease, or l) other, more rare conditions. The

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patient's general health status was also assessed on a 5-point scale and categorised as poor, fair, good, very good or excellent.

Mental health: Anxiety and depression were assessed using the 14-item Hospital Anxiety and Depression Scale (HADS) (Barth and Martin, 2005; Herrmann et al., 1995; Snaith, 2003). Scores ranging from 8 to 10 points were defined as sub-threshold anxiety or depression, while scores of 11 and higher were defined as threshold anxiety or depression.

Satisfaction with health and life in general: Satisfaction with health and satisfaction with life in general were assessed using two items of the questionnaire for life satisfaction (Fragebogen zur Lebenszufriedenheit, FLZ) (Fahrenberg et al., 2000). Each item included a 5-point Likert scale response set, using the anchors of 1=very unsatisfied and 5=very satisfied. Higher scores were indicative of greater satisfaction with health or life in general. Every patient was categorised as having either high (i.e. above the median) or low (i.e. below the median) satisfaction with health and high or low satisfaction with life in general.

Health locus of control: Health locus of control was assessed using the German health locus of control scale (Gesundheitsbezogene Kontrollüberzeugungen, GKÜ) (Westhoff, 1993), a 9-item German modified short-form of the English language multidimensional health locus of control scale, the most commonly used scale to assess health locus of control (Wallston and Wallston, 1981; Wallston et al., 1978). Response options ranged from "strongly disagree" to "strongly agree". The instrument assessed three dimensions of health locus of control beliefs (3 items each), including internal (i.e. health status perceived as controlled by self), external-social (i.e. health status perceived as controlled by others) and external-fatalistic (i.e. health status perceived as depending on luck or destiny). For every patient, each dimension was categorised as either high (i.e. above the median) or low (i.e. below the median).

2.4. Procedures

Participants were notified of the study by staff members upon their arrival at the clinic, and questionnaires were then distributed to participants immediately upon admission. A participant information sheet accompanied the questionnaires, which outlined the purpose of the study, what the study involved, the participant's rights, and researcher's contact details. The questionnaires were filled out by the patients on their own, and then collected by clinic staff once completed by the patient a few days later while patients were still in the hospital. Pertinent patient data were also collected from hospital records (as described below). Patients were free to decline participation in the study.

2.5. Statistical analysis

Statistical analysis was performed using IBM SPSS ® software (version 22.0, IBM, USA). Chi square tests were used to compare socio-demographic, clinical and psychological characteristics

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between patients that had ever used herbal medicine for their primary medical complaint and those who did not. A p-value of ≤ 0.05 was considered statistically significant.

The independent variables of herbal medicine use (hereon referred to as predictors; noting that these should not infer a causal relationship) were identified using multiple logistic regression analysis, of which a backward stepwise procedure was used with a Wald statistic p-value of ≤ 0.05 .

Continuous variables were categorised and adjusted odds ratios with 95% confidence intervals calculated; p-values ≤ 0.05 were considered statistically significant. Factors entered into the initial regression model were limited to those that were found to be significantly ($p \leq 0.10$) associated with herbal medicine use as determined by univariate analysis.

2.6. Ethics approval

The survey was conducted in accordance with the Helsinki Declaration. All the patients included provided written informed consent, and all data were analysed anonymously. In compliance with German law, ethics approval was not required as this was a secondary data analysis.

3. RESULTS

Of the 2,804 patients referred to the department over the 3-year study period, 2,486 (88.7%) agreed to participate in the survey. Of these respondents, 381 patients (15.3%) did not answer the question on herbal medicine use. Therefore, the analysis presented here is based on a sample of 2,105 patients (75.1% of referred patients).

Out of the 2,105 patients analysed, 1,670 (79.3%) were female, and the mean age was 52.8 ± 14.1 years. Most patients were diagnosed with chronic pain; the most commonly diagnosed conditions were spinal pain ($n=400$; 19.0%), headache ($n=248$; 11.8%), and fibromyalgia ($n=246$; 11.7%). Five hundred and sixty-nine patients (27.6%) were at least high school graduates, 555 (27.4%) were employed full-time, and 335 (16.5%) were employed part-time. 1,228 patients (59.0%) were in a relationship. Regarding lifestyle behaviours, 1,794 (87.0%) regularly consumed fast food, 345 (16.6%) regularly consumed alcoholic beverages, and 291 (20.4%) smoked at the time of the survey.

Eight hundred and eighty three (41.9%) participants reported ever having used herbal medicine for their primary medical complaint. Of these, 507 (57.4%) reported that herbal medicine had been helpful; 384 (43.6%) stated that herbal medicine were not helpful, and none (0.0%) reported these medicines as being harmful.

Univariate analysis revealed that herbal medicine use was higher in females, and in those with higher education, fibromyalgia, lung disease, sub-threshold anxiety, high internal locus of control, and those who did not eat fast food at all. By contrast, herbal medicine use was lower in patients

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over 65 years of age, who had spinal pain, at least good health status, regularly consumed alcohol and currently smoked, and had a high external health locus of control (Table 1).

Multiple logistic regression analysis found herbal medicine use to be associated with female gender, high school level education, suffering from fibromyalgia, lung disease or sub-threshold depression, having a high internal health locus of control and not eating fast food at all, while patients with spinal pain were less likely to use herbal medicine (Table 2).

High satisfaction with life and high internal health locus of control were both positively associated with the perception that herbal medicine was helpful, while smoking and the use of herbal medicine for headaches or irritable bowel syndrome were negatively associated with perceived helpfulness (Table 3).

4. DISCUSSION

This is the first study to analyse the predictors of herbal medicine use among inpatients in Germany referred to an internal integrative medicine department within an acute-care hospital. The study revealed a number of important findings, which are further discussed below.

The survey findings suggest that 42% of internal medicine patients had ever used herbal medicine to manage their primary medical complaint. The level of herbal medicine use reported among these patients, whilst comparable with prevalence rates described in Singapore (37%) (Lim et al., 2005), far exceeds the level of use reported in surveyed populations in the US (25%) (Barnes et al., 2004), Australia (23%) (Xue et al., 2007) and UK (9%) (Hunt et al., 2010). The estimate of herbal medicine use is also considerably higher than that reported in a 2008 population survey of 1,001 German adults (9.7%) (Bucker et al., 2008). Whilst the severity of this inpatient population's medical conditions and the generally poor health status are likely to be an important contributing factor to the relatively high level of herbal medicine use (Steinsbekk et al., 2011), there is a need to explore the extent to which this and other factors may impact herbal medicine utilisation.

The characteristics of herbal medicine users identified in this study are consistent with the characteristics of complementary and alternative medicine (CAM) consumers in general (Barnes et al., 2004; Hunt et al., 2010; Leach, in press; Sasagawa et al., 2008; Sirois, 2008; Xue et al., 2007); both herbal medicine users and CAM users appear more likely to be female, well-educated, adopt healthier diets and lifestyles, have a chronic disease, and have a high internal health locus of control. The latter finding aligns well with previous claims that CAM users generally want a greater sense of control over their health (Sirois, 2008; Thorne et al., 2002). To some extent, this is not surprising given that patients in medical settings often report feelings of disempowerment (Sampson et al., 2015); suggesting then that CAM may offer these patients an opportunity to circumvent such feelings, which could in turn, help to improve the patient experience.

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What was unclear from this study was why inpatients with spinal pain were less likely to use herbal medicine. An unlikely explanation for this is the absence of effective interventions given that several herbal medicines have been shown to be more effective than placebo at reducing low-back pain under randomised controlled trial conditions (Gagnier et al., 2016). This unusual finding warrants further investigation to determine if and why patients with spinal pain are perhaps not being offered herbal medicine as an effective treatment option.

Another somewhat unusual finding from our study related to the perceived effectiveness of herbal medicine among herbal medicine users. Most respondents indicated that herbal medicine had been helpful in managing their primary medical complaint, but paradoxically, a large proportion of users (44%) stated that herbal medicines were not helpful for the treatment of their primary medical complaint. This suggests that the perceived ineffectiveness of some herbal medicine preparations may not be a sufficient enough reason for someone to cease herbal medicine treatment in general. We suspect that the reasons for chronically ill persons choosing herbal medicine are probably as diverse as they are for the German adult population choosing CAM in general (e.g. recommended by a physician, desire to avoid drugs, ineffective/undesirable conventional treatment options) (Bucker et al., 2008), however, this remains speculative. A deeper exploration of the motivations for using herbal medicine may provide further insights into this paradoxical issue.

The generalizability of the study's results may be limited by the single-centre setting, and the patients' characteristics, including a slightly higher age and lower education level relative to the general German population (Bucker et al., 2008). Further, the survey did not assess the reasons for herbal medicine usage, attitudes towards herbal medicine, specific herbal preparations, the frequency of herbal medicine consumption, or the coverage of herbal medicines by health insurance. While subjective efficacy and safety of herbal medicine were assessed, the perceived benefits or harms of herbal medicine use were not investigated in more detail. Lastly, data for this analysis were collected between 2001 and 2004; this is because the data were collected primarily for internal quality assurance purposes, and were only recently made available to the research team for external evaluation and publication. Consequently, it is possible that the findings of this study may not reflect the current status quo; although, at the time of publication, a search of the literature indicated more recent data on herbal medicine use in chronically ill patients was still lacking - as such, the findings of this work still make an important and original contribution to the scholarship of the field. Finally the cross-sectional study design poses limitations regarding the ability to draw valid conclusions about the causality of effects.

Despite these limitations, the current study does extend previous findings on herbal medicine use in other populations, and the large sample size has facilitated new insights on the use of herbal medicine among hospital inpatients (including the moderately high prevalence of herbal medicine use in this population, and the relatively higher internal health locus of control and healthier diets and lifestyles of herbal medicine users). More recent research into the use of herbal medicine in

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chronically ill patients is warranted to examine whether the herbal medicine use within this population has changed.

While the current study provides important further insights regarding the herbal medicine user (particularly within the context of the hospital milieu), there are still a number of research questions that warrant further investigation, including: what are the motivations of hospital patients for using herbal medicine? Where do these patients source information on herbal medicine for their specific condition? How do these patients determine the quality of such information? And, do these patients involve their health care providers in decisions regarding the use of herbal medicine? Addressing these knowledge gaps should assist in informing future health policy, provider education and clinical practice, and in turn, improve the quality of care for users of herbal medicine, as well as hospital inpatients more generally.

5. CONCLUSION

This study reveals, for the first time, a substantial level of herbal medicine utilisation amongst German patients admitted to an integrative medicine clinic, with levels of use found to be relatively higher than a previous population study in Germany and other countries such as the USA, Australia and the UK. While the study identifies a number of predictors of herbal medicine use – which are not dissimilar to the predictors of CAM use more generally - it also uncovers new knowledge gaps in need of further investigation. Addressing these gaps will extend our understanding of the motivations of herbal medicine users, which will in turn help inform policy, practice and education initiatives to serve better the needs of this clinical population.

Editors' note: The editors' acknowledge the historic nature of the data however due to the dearth of published papers on the characteristics of herbal medicine and CAM users we consider that this paper adds to our body of knowledge.

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CONFLICT OF INTEREST

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We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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Table 1: Sociodemographic, clinical, and psychological characteristics of patients who used herbal medicine for their primary medical complaint (herbal medicine users) and those who did not (herbal medicine non-users)

Characteristics	Herbal medicine use (n=883), %	Herbal medicine non-use (n=1222), %	p-value
Age group			
Less than 30 years	6.0	5.7	0.851
30 to 39 years	14.7	13.1	0.305
40 to 49 years	19.8	19.6	0.956
50 to 64 years	41.0	38.0	0.161
65 years or greater	18.5	23.6	0.005
Gender			
Female	84.7	75.5	<0.001
Education			
High school graduate	32.8	23.8	<0.001
Employment			
Full-time	26.5	28.1	0.450
Part-time	16.0	16.9	0.586
In a relationship	58.0	59.7	0.443
Main diagnosis			
Fibromyalgia	14.7	9.5	<0.001
Spinal pain	14.6	22.2	<0.001
Headache	11.8	11.8	1.000
Other pain	9.3	11.9	0.055
Osteoarthritis	8.8	9.3	0.759
Arthritis	7.7	5.6	0.059
Lung diseases	6.3	4.3	0.046
Inflammatory bowel disease	5.8	4.3	0.125
Irritable bowel syndrome	4.2	2.4	0.022
Hypertension	2.5	3.9	0.084
Ischaemic cardiac disease	1.0	1.2	0.836
Other conditions	13.3	13.6	0.846
Health status			
Good, very good or excellent	15.0	17.8	0.085
Mental health			
Subthreshold anxiety	28.3	23.7	0.022

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Threshold anxiety	35.5	35.0	0.852
Subthreshold depression	26.4	22.2	0.033
Threshold depression	22.4	21.7	0.707
Satisfaction with health / life			
High health satisfaction	70.5	72.4	0.351
High life satisfaction	82.5	84.9	0.131
Health locus of control			
High internal	62.5	55.4	0.001
High external-social	62.5	71.2	<0.001
High external-fatalistic	61.5	63.9	0.380
Smoking status			
Current smoker	17.4	22.6	0.016
Past Smoker	30.8	33.4	0.328
Alcohol use			
Abstinent	42.7	40.0	0.240
Regular use	15.0	17.8	0.095
Fast food consumption			
Abstinent	6.1	2.8	<0.001
Regular use	85.8	87.8	0.185

Table 2: Independent predictors of herbal medicine use for the patient's primary medical complaints (Results from multivariate logistic regression analysis)

Predictor variables	p-values	Adjusted odds ratios	95% Confidence interval
Fast food abstinent	<0.001	3.00	1.73 - 5.22
Gender	<0.001	2.03	1.50 - 2.75
Lung diseases	0.017	2.00	1.13 - 3.52
High school graduate	<0.001	1.65	1.28 - 2.13
Fibromyalgia	0.007	1.65	1.15 - 2.36
High internal health locus of control	0.017	1.33	1.05 - 1.68
Subthreshold depression	0.042	1.32	1.01 - 1.72
Spinal Pain	0.039	0.73	0.55 - 0.98

Table 3: Independent predictors of the helpfulness of herbal medicine for the patient's primary medical complaints (Results from multivariate logistic regression analysis)

Predictor variables		p-values	Adjusted odds ratios	95% Confidence interval
High internal health locus of control		<0.001	3.58	2.26 - 5.68
High life satisfaction		0.001	2.62	1.51 - 4.57
Current smoker		0.008	0.48	0.28 - 0.83
Irritable Bowel Syndrome		0.041	0.35	0.13 - 0.96
Headache		<0.001	0.33	0.18 - 0.60