‘Other-unproven’: US research and its implications for complementary therapies in the UK

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Abstract:

An American study has concluded that people with cancer who receive complementary medicine (CM) have a twofold greater risk of death compared with patients who had no CM. The Yale University study is presented as an assessment of ‘complementary’ rather than ‘alternative’ therapies, but this critical analysis

suggests it fails to differentiate between the two approaches to the use of unconventional interventions. It also fails to address the complex factors involved in its authors' question: 'What patient characteristics are associated with the use of CM for cancer and what is the association of CM with treatment adherence and survival?'.

By considering the US study in the context of conditions and developments in the UK, this article offers insights into ways appropriately trained and regulated complementary therapists could play a useful role in new models of care. It also identifies areas for further investigation.

Background*:*

Doctors at Yale School of Medicine (Johnson et al 2018a, 2018b) have conducted a retrospective observational study drawing on data from the US National Cancer Database on more than 1 million patients who had been diagnosed with non-metastatic breast, prostate, lung and colorectal cancer. They first identified people who had received one or more conventional cancer treatments (CCTs), such as surgery, chemotherapy, radiotherapy and hormone therapy, then searched this group for people whose notes carried the code 'Other-unproven: cancer treatments administered by nonmedical personnel'. Their data analysis, which concerned overall survival rates and adherence to treatment, showed that this subgroup had a higher refusal rate of additional conventional treatment compared with people who did not have the other-unproven code on their records. Johnson et al's (2018b) study concludes that 'patients who received CM were more likely to refuse additional CCT and had a higher risk of death'. This article examines: the assumptions the authors made; the conclusions they drew; and the implications for research into, and use of, complementary therapies in supportive and palliative care in the UK.

Alternative v complementary

The researchers had previously conducted a similar study into survivorship among people with nonmetastatic cancers drawing on the same database (Johnson et al 2018a). In this study, they examined the data of patients who had the other-unproven code in their notes but had not undergone CCT. These cases were defined as examples of ‘alternative medicine’. A main purpose of Johnson et al’s (2018b) study was to differentiate between alternative medicine and complementary medicine (CM), whereby patients who had received CM were defined as those who had also received CCT but had the other-unproven code in their records.

The British Medical Association (BMA) defines complementary therapies as non-conventional treatments that ‘work alongside or in conjunction with orthodox medical treatment’ and alternative therapies as those ‘given in place of orthodox medical treatment’ (BMA 1993). So, if a patient refuses or delays a CCT in favour of a non-conventional therapy, the change in intent means the therapy is regarded as ‘alternative’ rather than ‘complementary’. So, according to the BMA’s definitions, a patient who has a reiki session during chemotherapy is receiving a nonmedical intervention that is complementary to the mainstream treatment. Even if the chemotherapy unit offers reiki as part of a deliberate strategy to encourage patients to complete their courses of chemotherapy, the treatment is still integrated and therefore complementary. But if the reiki treatment is given instead of interventions recommended by the oncologist, it should be regarded as alternative.

The researchers observe that their work ‘demonstrates that patients who use alternative medicine and CM are often behaving similarly in refusing conventional treatment.’ But at the moment where mainstream cancer treatment is refused in favour of a non-conventional therapy, that therapy is no longer complementary. The Yale researchers acknowledge the existence of this transitional moment: ‘It is possible that clinicians were more likely to document the use of CM when patients were using noteworthy therapies that may have resulted in refusal of CCT.’ In effect, the clinicians were logging the moment when the shift of patients from CM to alternative medicine took place. However, the researchers fail to grasp the significance of this moment, as is evident in their claim that users of complementary and alternative approaches ‘are often behaving similarly in refusing conventional treatment’. This contradiction of terms is embedded in the headline of the Yale Cancer Centre’s (2018) press statement: ‘Replacing conventional medicine for complementary therapy can decrease survival’ – a ‘replacement’ is an alternative, not an adjunct.

The Yale studies indicate that alternative medicine is culpable for poorer outcomes, but they cannot prove the guilt of complementary therapies. In the press release, co-author Cary Gross calls for further research, saying: ‘The sources of misinformation need to be better understood.’ This is necessary, but the study is itself a source of misinformation.

Cultural differences

People with cancer in the UK routinely access complementary therapies to help them cope with side-effects and stress, enhancing quality of life and improving treatment compliance (Baldwin and Woodhouse 2011). These are not ‘cancer treatments’, however. In the UK, only doctors, nurses and pharmacists can promote or prescribe cancer treatment, and the administration of ‘unproven cancer treatments by nonmedical personnel’ is against the law. If a therapist claims their intervention can cure cancer, they are committing an offence under the Cancer Act 1939, Section 4.

In the US, the emphasis is placed on freedom of choice, and this includes the freedom to access unconventional therapies for the treatment of cancer. Regulation varies from state to state (World Health Organization 2001). Consequently, alternative therapies to treat cancer are so prevalent their use warrants a code in patients’ medical notes. Moreover, US patients over the age of 21 who use Medicare and have a condition that could cause death within six months are faced with a choice: pursue a cure or access palliation. Their Medicare insurance does not cover both (Centers for Medicare and Medicaid Services 2018).

The researchers observed that logs of other-unproven treatment codes ‘differed significantly by facility’, which could be because some treatment facilities have lower thresholds for deciding which therapies are significant enough to record or because clusters of people using the facilities were particularly drawn to other-unproven treatments. Patients identified in the study as ‘CM users’ tended to be younger, well-off, well-educated and otherwise healthy women from Arizona, California, Hawaii, Oregon and Washington, where there are high concentrations of complementary and alternative medicine (CAM) schools and state legislation favouring CAM (Barnes et al 2004). Whether these women had been targeted by commercial enterprises exploiting lax state laws warrants further investigation. The researchers rightly call for action to ensure that patients ‘aren’t being sold a false bill of goods’ and warn against the marketing of alternative therapies as effective cancer treatments. Misinformation moves across international boundaries, often fuelled by social media networks, and many ‘healthy living’ marketing scams prioritise selling product over its responsible use.

Study design

The researchers claim that their study aims to ‘investigate factors associated with the selection of CM’, but they did not gather data for that purpose. Theirs is a secondary analysis of a database of medical records.

‘Curable’ cancers

Their claim that the patients in the study have curable cancer is based on their exclusion of patients with metastatic disease at diagnosis, stage IV disease in the sample years, those who chose ‘upfront treatment with palliative intent’ and those with ‘unknown’ treatment status. The researchers say they were unaware of many aspects of the patients’ cancer experience that could influence survival, including the prognoses of specific cancers, details about stopped or dose-reduced treatments, and the burden of the disease and its treatment. There is also no record of the patients’ treatments for health problems other than cancer. All these factors may have had a significant influence on individual decisions to discontinue, delay or avoid conventional treatment.

The continuation of complementary therapies to support a person who has decided to discontinue curative treatment cannot be compared with the use of non-conventional therapies in the treatment of the cancer itself. The Yale study highlights the dangers of failing to adhere to conventional treatment plans. Patients must have a full grasp of these dangers to make informed decisions about their treatment. But conventional treatments can be risky, challenging and traumatic – as medical professionals are duty-bound to explain. Each patient must constantly weigh risk against benefit on the basis of full and objective information, and make their own decisions along the full course of their journeys. But this process is not addressed by the study.

Therapies

The researchers draw their conclusions despite an ‘absence of information regarding the type and total number of CM modalities used’. They claim that ‘CM and alternative medicine likely represent entities along a continuum’, but as has already been established, it is the application of a therapy, not the therapy itself, that defines whether an intervention is complementary or alternative. Rather than using the idea of a continuum, Hawks and Moyad (2003) refer to guidance from the US National Center for Complementary and Alternative Medicine to suggest five categories of other-unproven interventions: mind-body, such as meditation; biologically-based, such as herbalism; physical, such as massage; energy-based, such as reiki; and alternative medical systems, such as homeopathy. Each therapy has, or lacks, its own evidence base, as well as indications, contraindications, risks and benefits. Some, such as those involving ingestion of unverifiable substances, are inherently alternative and cannot be adapted to complement conventional care. Others, such as massage and cognitive behavioural therapy, have an evidence base that compares favourably with the benchmarks of mainstream medicine.

Each interaction between therapist and patient multiplies the complexity of the issue under scrutiny. The nature of the therapeutic relationship (Budd and Ursula 1994, Fox 2008); the quality of training and regulation, and its influence on the therapist (Wilkinson and Gale 2015); the timeline of each patient's journey; and the juxtaposition of conventional and unconventional therapies are all important factors in the evaluation of the safety, or otherwise, of each therapy when it is applied as complementary or alternative medicine. The full picture can only be ascertained by applying a range of research methods to these crucial details.

Biomedical v biopsychosocial

The study is grounded in the biomedical model of care, which assumes the main objective of treatment is survival. But, for some people already coping with complex, chronic conditions, their rejection of further aggressive cancer treatment is a positive choice: quality of life over quantity of life. Developments in cancer nursing follow the biopsychosocial model of care, which offers a realistic framework for ways of living with and beyond cancer. Unconventional therapies can appear attractive to some patients, and the people they meet can have a profound influence on their choices and opinions. The researchers point to evidence suggesting that a less hopeful cancer prognosis is associated with use of non-conventional therapies. They consider the possibility that late diagnosis occurs when people believe that unconventional treatments make mainstream scanning and diagnostic procedures redundant. If this is the case, and the people concerned are undergoing non-conventional therapies to avoid mainstream health interventions, their therapies can be described as alternative rather than complementary.

The researchers conclude: ‘For patients with curable cancers who are inclined to pursue complementary treatment methods, timely adherence to all recommended conventional therapies should be strongly advised.’ Similar advice appears in the codes of conduct observed by accredited complementary therapists on the UK’s voluntary registers. Examples of good practice, where complementary therapists work as part of hospice multidisciplinary teams, are extensive, but there are many reasons why people with life-limiting conditions do not access such services and seek, either by choice or necessity, therapies from non-hospice-based providers. A deeper understanding of the complex interplay of these factors requires a complementary blend of quantitative and qualitative analysis (Dew 2012). The Yale studies are a starting point for this analysis in that they make clear the need for further research into what happens when people with cancer engage in non-conventional therapies.

The Yale researchers imply that complementary therapy is a kind of ‘gateway drug’ that prompts desire for more extreme non-conventional interventions and a rejection of conventional care. Integrative medicine has been described as ‘a way of smuggling alternative practices into rational medicine by way of lowered standards of critical thinking’ (McLachlan 2010). This claim also requires further investigation.

Implications for practice

In the UK, complementary therapists have been collaborating with mainstream health providers for over a decade to improve treatment compliance and quality of life for people with cancer. By applying their experience of cancer care to other patient groups, they have developed services tailored to the needs of a wide range of people, including those with dementia and other neurodegenerative disorders. Their efforts address problems for which mainstream medicine has few answers, thereby relieving pressure on hard-pressed health and social care services and supporting self-care, a key theme of NHS Sustainability and Transformation Plans (King’s Fund 2017).

With the correct continuing professional development and support, complementary therapists could be ideally placed to inform and educate people accessing their services. In this context, the NHS Institute for Innovation and Improvement (2007) document Thinking Differently states: ‘Workforce planning should begin with the needs of the patient before looking at the skills and competencies required to meet these needs.’

A framework for excellence is provided in National Guidelines for the Use of Complementary Therapies in Supportive and Palliative Care (Tavares 2003), and the Professional Standards Authority for Health and Care (PSA) accredits voluntary registers of complementary therapists who commit to standards and procedures. Bodies accredited by the PSA include the Complementary and Natural Healthcare Council (2018) and Federation of Holistic Therapists (2018). Their codes of conduct ban members from claiming to diagnose, treat, heal or cure medical conditions, or from advising a client to stop medication or treatment that has been prescribed or recommended by a statutorily regulated healthcare professional. They instruct therapists to direct their clients to their health professionals to discuss treatment decisions and to keep their clinical team informed of their use of complementary therapies. Therapists are obliged to make sure they do not give treatments a client’s health professional has advised against.

The PSA and Royal Society for Public Health (2017) recognise the potential of accredited complementary therapists and have outlined a framework to support them in a public health role. Complementary therapists often have regular and relatively long sessions of contact with clients. The report identifies the potential within those sessions for the therapists to support their clients to make positive behaviour changes. The Health Education England (HEE 2018) initiative Making Every Contact Count offers training packages to maximise the potential of day-to-day interactions such as the provision of complementary therapy. Meanwhile, Public Health England (2017) is re-evaluating education, training and development within the health and social care support workforce. All these initiatives have potential to facilitate the appropriate involvement of complementary therapists in the wider health workforce.

The RCNi Cancer Nursing Practice conference in Birmingham in May 2018, entitled Living With And Beyond, discussed new frameworks of care which could have the potential to utilise appropriately trained and regulated complementary therapists. Nurse specialist Sarah Orr and nurse consultant Natalie Doyle discussed the practicalities of delivering ‘individualised plans of care underpinned by self-management with support from the right person, at the right place, at the right time’, as set out by Macmillan Cancer Support (2013). It may well be that hospice and hospital staff can identify complementary therapists who are already working alongside them who have the potential to play a supporting role in the Recovery Package outlined in the 2013 Macmillan report. If complementary therapists are experienced, well-prepared and supported, they can encourage patients to persevere with a structured, nurse-led self-management programme.

Macmillan Cancer Support’s chief of nursing and allied health professionals Karen Roberts is in charge of monitoring skill mix and identifying new roles in cancer care as the ‘treatable, but not curable’ cancer category expands, increasing the pressure on resources. In the document Cancer Workforce in England (Macmillan Cancer Support 2018), she describes the key role of the ‘nonmedical adult cancer workforce’, and identifies bands 3 and 4 cancer support workers for development.

A workshop on stratified follow-up care at the May 2018 RCNi Cancer Nursing Practice Conference, led by advanced care practitioner Claire Marsh and public health specialist Hazel Brodie, featured specific support tasks at band 4 that would lend themselves to the talents and accessibility of competent complementary therapists with the appropriate training, regulation, and mentoring. With the appropriate competencies and training, and nurse specialists as mentors, complementary therapists could be part of this system of support.

There is an established demand for complementary and alternative medicine in cancer care that is unlikely to abate as survivorship increases, and care pathways become more complex and patient-led. The engagement, training and regulation of complementary therapists could make a significant contribution to new models of care. Decision-makers should look at the Yale research with a critical eye and augment quantitative analysis with a deeper investigation into the qualitative aspects of complementary therapies in palliative care. Failure to do so could halt the development of integrated therapies that relieve some of the caring burden from overstretched NHS services, and put pressure on charities that attract funding as a result of their responsible and measured provision of complementary therapies.

Conclusion

The researchers' attempt to make the important distinction between alternative medicine and CM is welcome and timely, but fails to differentiate between the two appropriately. Information about individual patients in the study is insufficient to draw conclusions about their use, or the consequences of use, of non-conventional therapies because it was not collected with the purpose of the study in mind.

More mixed-methods research is required, therefore, to explore the patient characteristics associated with the use of CM for cancer, and the association of CM with treatment adherence and survival.

When interpreting the study's findings, caution is also required because of differences in culture between US and UK cancer care, and CAM use. Developments in patient-centred care in the UK have created a place for well-educated and regulated complementary therapists, but this could be jeopardised were the researchers' conclusions to be taken at face value. Research is required to identify the education and regulation needed to integrate existing and future complementary therapists into new models of care.

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