The creation of an informed consent form for osteopaths in clinical practice using a consensus process

NCOR Exeter Research Hub


Introduction

Informed consent is believed to be a relatively new response to growing biotechnological and treatment interventions. Documentation from Greek and Roman periods has been identified that shows the need for patient approval before the intervention of a doctor1. The introduction of Fitness to Practise guidelines by the General Osteopathic Council® underlined the importance of informed consent within osteopathic practice. A number of osteopaths had started to create their own versions of consent forms and the Exeter research group has examined the literature surrounding consent to create a consensus document that could be helpful to members of the osteopathic profession wishing to use a consent form.

What is informed consent?

Informed consent may be described as "the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications"2. The importance of consent was raised following the revelation of experimental atrocities during the Nuremberg trials in 1945. The components of informed consent can be described in the following way:

- The diagnosis, prognosis and likely prognosis if a condition is left untreated.
- Any uncertainty concerning the diagnosis and further investigations required.
- Management strategies that could be adopted including the possibility of no treatment.
- The proposed techniques to be used in diagnosis and treatment, both osteopathic and adjunctive e.g. acupuncture, heat or ice.
- The intended benefits of the diagnostic and treatment interventions in balance with the potential risks3,4.

Methods

A literature search was undertaken. This examined literature from a variety of health care professions and concentrated on consent associated with clinical practice rather than consent related to research. A number of electronic databases were accessed including PubMed, AMED, CINAHL, PEDro and OSTMED. Hand-searching of paper copies of the British Osteopathic Journal and the Journal of Osteopathic Medicine was also carried out. Attention was paid to the development of consent forms in other health care professions and the recommendations for key information that should be disclosed as part of the consent process. Members of the Exeter research hub also brought along existing consent forms they used in clinical practice. A draft consent form was created by the hub; this was piloted among the group, refined and then further refined following group discussion5. A final version of the consent form was created and is shown below in the results section.

Results

A series of draft consent forms were created and piloted. A completed consent form was created and is shown below.

What information was identified to be commonly disclosed as part of the informed consent process?

What information now exists concerning what is needed to meet the key requirements of informed consent.

What information was identified to be commonly disclosed as part of the informed consent process?

What information was identified to be commonly disclosed as part of the informed consent process?

References: