University of BRISTOL

CENTRE FOR CHILD & ADOLESCENT HEALTH

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Mr James Berry MP
Member of Parliament for Kingston & Surbiton
255 Ewell Road
Surbiton
KT6 7AA

27th September 2016

Dear Mr Berry,

Thank you for your letter dated the 13th of September 2016.

I take informed consent very seriously. The consent process for MAGENTA trial has been through rigorous peer review and ethical review. The process of obtaining consent, our patient information sheets, assent forms and consent forms have been reviewed by the Regional Ethics Committee who granted a favourable ethical opinion (REC number 15/SW/0124). We have followed current guidance relating to obtaining informed consent from children. In addition, we record recruitment consultations to ensure the information provided is clear and balanced. Your constituent will be aware of the processes as our ethics approvals, patient information sheets, assent and consent forms can be found on the MAGENTA website (http://www.bristol.ac.uk/ccah/research/childdevelopmentdisability/chronic-fatigue/magenta-trial/). I have enclosed our protocol which has been peer reviewed, published and is available as an open access document.

Your constituent feels we should have warned patients about the “increasing evidence that it [GET, Graded Exercise Therapy] is potentially damaging.” I can reassure you that in fact, there is increasing research evidence that GET does not harm patients. The best quality evidence is a systematic review of the literature. Systematic reviews collect all the evidence from all studies to answer important questions. I have enclosed the Cochrane systematic review of exercise therapy for chronic fatigue syndrome. This independent review examined 8 randomised clinical studies with data on 1518 patients which concludes “exercise therapy was more effective than passive treatments or no treatment”, and had a “positive effect on people’s daily functioning”, and so on. It also found “exercise therapy was not found to worsen symptoms for people with CFS”.

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Despite the increasing evidence that GET does not harm patients, we have been proactive in checking this is true in children. Our protocol describes the effort we have made to prospectively collect data on adverse events and explore whether there is a difference in the proportion or children who get worse in each arm. I am pleased to report that there is no evidence of harm in our trial to date. We will be reporting on this shortly.

In addition to this evidence, we are also asking participants in MAGENTA for their views and experiences of the trial. This takes the form of integrated qualitative studies (interviews) with children and their parents and we intend to publish data to describe this in detail. Preliminary results suggest that children, young people and their parents are actually very positive about their experience of GET.

Importantly, I would also like to point out that NICE recommends GET as one of the treatments we should offer children with CFS/ME. As you know, the processes used by NICE are rigorous and include further independent review of the worldwide literature.

Thank you for your interest in our research. I lead one of the few remaining research teams in the UK studying CFS/ME and trying to understand this important condition and how best to treat it. I am passionate about improving the outcomes for children with CFS/ME. MAGENTA is a study that children with CFS/ME want to take part in because they want to know whether GET is effective or not. It saddens me that for such an important illness, there is still a group of people campaigning to stop high quality research.

Yours sincerely

Professor Esther Crawley
BA (Hons), BM, BCh, FRCPCH, PhD