Designing a diet interventional study for autoimmune rheumatic disease: asking patients what they think

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Background: Using diet to help alleviate disease symptoms or control drug side effects in patients with autoimmune rheumatic disease is gaining renewed interest but little is known about what patients think about using diet to control their disease or what dietary interventions they would prefer. Our aim is to obtain patient input in the design of a potential diet interventional study in autoimmune diseases and compare the experiences and ideas of patients relating to diet from various ages and disease groups during a patient and public involvement and engagement (PPIE) event.

Methods: 35 adult and young adult patients with Sjögren's syndrome and/or systemic lupus erythematosus were approached to participate when attending outpatient clinics at UCLH. 10 female patients with age range from 18 - 80 agreed to take part in a face-to-face PPIE event

held at UCL. During group discussions, patients were split between three groups, each facilitated by 3-4 members of the research team with different backgrounds and skills (clinical, basic science and PPIE expertise). The main themes discussed were: 1) barriers to taking part in a research study investigating the role of diet in autoimmune disease 2) the ideal clinical trial design 3) the most appropriate patient information leaflet design for this study.

Results: The majority of patients (80%) would agree to participate in a diet-related study for up to 12 months including completing questionnaires, conducting interviews and providing blood samples. The qualitative analysis of the group discussions identified the following themes: recording the daily food intake either using an app or a diary was acceptable to patients, there were concerns about drug interactions and diet; however, patients did not think that their disease would affect their ability to take part in a diet interventional study. As a means of communicating study updates, the patients preferred to be contacted by e-mail, letter, text or phone call. In terms of intervention allocation, patients found it acceptable to be on the placebo arm of a study, to go on a diet for up to 6 months or to be administered a combination of interventions (diet, food supplements in tablet). Patients preferred to be assessed monthly or when attending outpatient clinics, and would complete questionnaires, even if lengthy. We asked patients to assess leaflets commonly available from charities and the NHS providing diet advice. Most patients had not seen such leaflets previously and suggested including recipes and a section for vegetarian food.

Conclusion: This PPIE event provided valuable ideas to improve potential study design ensuring a diet intervention would be patient centred. The unexpected findings were the high acceptability of questionnaires and patients’ acceptance of a placebo intervention. Further PPIE follow-up events are planned aiming to discuss trial protocols in detail.