

Bioscience
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Knowledge Transfer Network

Knowledge Transfer Networks
Accelerating business innovation;
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CASE STUDY



Newcastle
University

Newcastle:
A great place to do
food business

**KNOWLEDGE-BASED
BIO-ECONOMY
OF THE 21ST CENTURY**

Providing the Science Behind the Claim: Human Intervention Trials for Food Products and Ingredients

There is a growing interest in food not just as sustenance but also to deliver bioactives for increased individual and population wellbeing. The food industry is interested in developing products aimed at improving brain, intestinal, cardiovascular, metabolic or immune functions in many populations, including the healthy, young, the elderly and those with increased risk of heart disease or diabetes.

Human Nutrition Research Centre

Newcastle University formed the **Human Nutrition Research Centre (HNRC)** in 1994 to provide a single focal point for its wide-ranging activities in the field of nutrition, diet and health. The centre provides a wealth of expertise, from fundamental studies of nutrient-gene interactions and effects on cells, to the design of public health initiatives and studies of the health effects of whole grain foods, in the food and nutrition sectors.

The independent verification of health and nutrition claims for products and ingredients has become of increasing importance in the food markets over the last decade. This trend towards scientific rigour has been strengthened within the EU by legislation and is providing a spur to industry to provide the best evidence base possible for consumers who are interested in the health-promoting properties of food and diet.

Intervention Trials and Providing Scientific Evidence for Health Claims

The EU have recently introduced legislation to ensure that any nutrition and health claims made for foods are based on sound scientific evidence (Regulation EC 1924/2006) This often requires controlled studies in humans, using the appropriate dose and designed so the results are relevant for the intended target group. However, most published studies on foods and food supplements were not designed for this purpose and so there is a need to design and perform new studies specifically designed to meet the legislative requirements.



The **HNRC** has experience of a wide range of intervention studies and has established specific expertise in the design and performance of food and supplement trials with healthy subjects. Volunteers receive foods or other products to supplement their habitual diet, and are then tested for changes in a range of health indicators. This experience provides a sound base for the design and delivery of relevant studies to support health claims.

Recent trials carried out at Newcastle illustrating the range of experience and technical approaches available.

WHOLEHeart study

www.wholeheart.org.uk

to test the effect of incremental increases in wholegrain consumption on risks for cardiovascular disease: 200 volunteers in Newcastle, 16 weeks intervention with up to 6 portions of wholegrain food per day. *2005-2008.*

The Selgen study

www.fasebj.org/cgi/rapidpdf/fj.07-8166comv1

considered the role of genotype and gender on response to selenium supplementation: 75 volunteers, 12 weeks intervention consisting of genotype testing and 100µg sodium selenite per day for 6 weeks followed by wash out for 6 weeks. *2004-2006.*

The FINGEN study

www.ncl.ac.uk/biomedicine/research/groups/publication/57210

looking at whether gender and genotype alters cardiovascular biomarker response to fish oils: 150 volunteers in Newcastle, 48 weeks intervention consisting of 3 periods with 0.7 or 1.8g fish oil per day or placebo, each for 8 weeks, with 12 weeks of washout between treatments. *2003-2006.*

The Fruit at Work study

www.fruitatwork.org

aims to determine whether provision of free fruit in the workplace is a useful approach for increasing fruit intake: 407 volunteers, 20 weeks intervention with or without provision of free fruit in the workplace. *2008-2009.*

GrainMark study

www.grainmark.org

investigating biomarkers of whole grain intake: 67 volunteers, 16 weeks intervention with up to 6 portions of rye or wheat wholegrain foods per day. *2007-2009.*

Vitamins and minerals study

http://www.nutrition-neuroscience.co.uk/research_and_facilities/cognitive_testing/vitamins

from Northumbria University: 220 female volunteers reporting subjective fatigue. 9 weeks intervention with multi-vitamin/minerals or placebo daily. *2008-2009.*



Newcastle NIHR Clinical Research Facility

The Clinical Research Facility (CRF)

www.ncl.ac.uk/crp/facilities/nrcf

was opened in 2005 to support clinical trials involving Newcastle University or Newcastle upon Tyne Hospitals NHS Foundation Trust. This resource provides dedicated patient-care facilities and practical support to develop and conduct research projects to world-class standards. The staff are experienced in carrying out trials in a wide range of clinical areas and bring the same attention to detail and high standards of care to Newcastle's nutrition studies.

The Clinical Research Facility offers Newcastle researchers facilities for the comfortable handling of subjects during trials, excellent facilities for downstream measurements and a network for development of nutrition-based studies for specific patient groups.

The resources include:

- 10 en-suite monitored in-patient beds;
- 6 fully-equipped consulting rooms;
- 6-seated recliner room;
- Project team of 10 highly experienced and dedicated research nurses
- State-of-the-art exercise suites;
- Measurement of body composition, flow mediated dilatation, bone density etc.;
- Blood sample preparation and analysis of biomarkers of health;

A successful human intervention study not only requires good design and excellent facilities but subjects with the appropriate health and nutrition profile and sufficient commitment to ensure completion. Newcastle's **Human Nutrition Research Centre** can provide this essential component with:

- A database of almost 1000 volunteers
- Volunteer groups with UK average nutrient intakes
- Tried and tested procedures for delivery of nutrition studies
- Low dropout rates (15% or less)

The **Human Nutrition Research Centre** sits at the centre of an excellent range of food-related activities and expertise in Newcastle which can be called upon for collaborative programmes.

Areas of particular strength include impact of foods and medicines on dental health at the Dental School; consumer perception of novel and functional foods Newcastle University Marketing Group and effects of foods on brain function and athletic performance at Northumbria University. The Food Quality and Health Group specialise in the food supply chain and can assist with quality control or product development. Finally, Newcastle University is part of The Medicinal Plants Research Group with expertise in the analysis and testing of medicinal plants and herbal products.



To complement this strength and breadth across the food-related industries, Newcastle has launched two new industry-oriented MSc programmes for September 2009 entitled: 'Medicinal Plants and Functional Foods' and 'Advanced Food Marketing'.

Science Services

Newcastle Human Nutrition Research Centre has gathered together a breadth of expertise in the scientific validation of food products and ingredients for industry and the public health sector. It has a flexible approach to development of trials and funding models for these studies including consortia formation; CASE and other studentships or simple contract research.



For more information on one or more of these areas please see contacts below:

Newcastle Human Nutrition Centre: <http://www.ncl.ac.uk/hnrc>.

Food and nutrition intervention trials:

Prof Chris Seal, chris.seal@ncl.ac.uk, tel. 0191 222 7650

Marketing studies and MSc 'Advanced Food Marketing':

Miss Mary Brennan, mary.brennan@ncl.ac.uk, tel. 0191 222 6930

Oral Health aspects:

Dr Anne Maguire, a.maguire@ncl.ac.uk, tel. 0191 222 8564

Medicinal plants and MSc 'Medicinal Plants and Functional Foods':

Dr Ed Okello, e.j.okello@ncl.ac.uk, tel. 0191 222 5175

Testing of brain function and athletic performance:

Prof David Kennedy, david.kennedy@unn.ac.uk, tel. 0191 243 7720

Clinical trials in general:

Prof Mark Walker and the **CRF team**, projects.crf@ncl.ac.uk, tel. 0191 282 0070



Contacts information

Bioscience for Business KTN
IT Centre
York Science Park
Heslington
York
YO10 5DG

Phone: 01904 561582

Fax: 01904 567782

E-mail: info@biosciencektn.com

Visit

www.biosciencektn.com

and follow the self-registration
instructions to receive

free membership

www.biosciencektn.com
info@biosciencektn.com