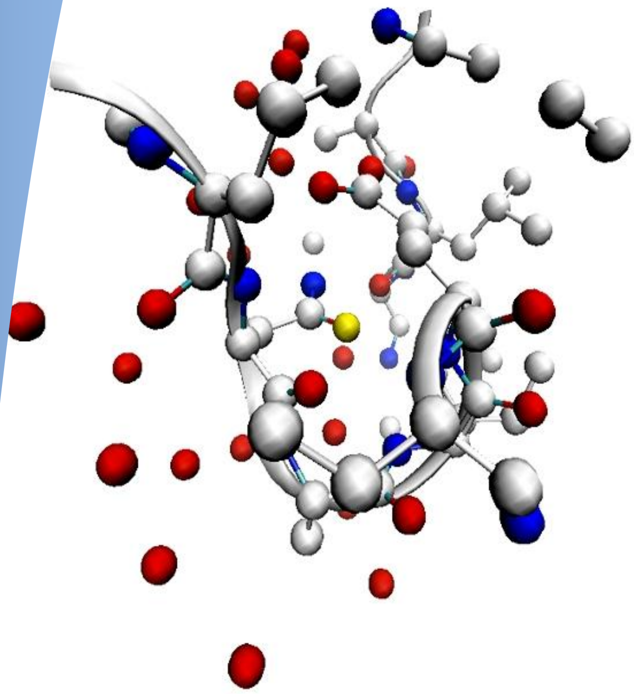
A New Era in ME/CFS Research

An Opportunity for Major Progress in Diagnosis, Treatment and Research into Myalgic Encephalomyelitis

Invest in ME (UK Registered Charity Nr. 1114035)



Myalgic Encephalomyelitis

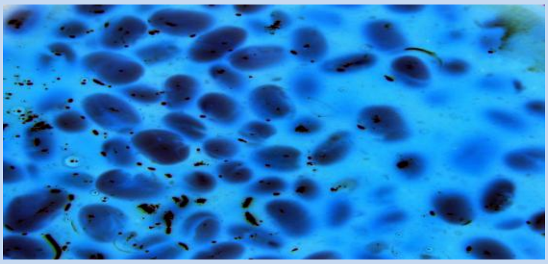
Myalgic Encephalomyelitis (ME or ME/CFS) is recognised by the World Health Organisation, and accepted by the UK government, as a neurological illness (under WHO code ICD 10 G93.3).

In the UK it has been estimated that 250,000 may be affected by the illness – over twice the number compared to MS patients and four times the number of HIV/AIDS patients.

ME/CFS is the most common cause of long-term absence from school through sickness. Around 75% of people with ME/CFS describe a sudden onset to their illness, often dating back to an acute viral infection.

From 1st November 2010 the UK Department of Health is instituting a permanent lifetime ban on people who have/have had ME/CFS from donating blood.

Little public funding of biomedical research into ME/CFS has been provided to date. Despite this over 4000 biomedical research papers exist from mainly privately-funded research which shows the multi-system, complex nature of an organic illness which may be infectious.



A VISION FOR THE FUTURE

Recent biomedical research and advances in knowledge and treatment regarding Myalgic Encephalomyelitis have brought more urgently needed awareness of this disease. In the East Anglian region of UK an opportunity now exists to bring real benefit to patients and establish a unique capability which will attract attention and recognition from across UK and Europe.

BACKGROUND

People with ME need early and correct diagnosis, proper treatment and advice. The current status of services for people with ME and their families in the UK is poor with little knowledge of current biomedical research and possible treatments being made available to patients or healthcare staff.

Thirteen clinics were set up by the government to treat ME/CFS but these are effectively only chronic fatigue facilities, mainly led by psychiatrists and occupational therapists offering inappropriate therapies such as cognitive behaviour therapy or graded-exercise. These therapies may be harmful to ME/CFS patients and which have no good evidence base to support widespread usage for people with ME/CFS.

Currently there is no service for people with ME/CFS, especially those who are severely affected, a group consisting of 25% of the ME patient population. The severely affected ME patients are mostly ignored by healthcare services.

In Norfolk, Suffolk and Great Yarmouth alone it is estimated that over four thousand people may suffer from ME – across the age group from age six and above, and affecting people of all social backgrounds. A consultation process begun in 2006 between these PCTs and patient representatives has achieved nothing and was criticised by the HOSC recently. The clinical consultant lead at the CFS Clinic at Great Yarmouth has been retired with no replacement leaving only occupational therapists and part time GPs with special interest being used to provide advice on management of ME.

There is no training available in the latest biomedical research (with the annual Invest in ME biomedical research conferences offering the only platform for disseminating current research).

This has resulted in ME patients having no service and there being little progress in attracting new researchers or clinicians to study the disease.

The dangers for people with ME having no proper clinical examination and no access to possible treatments is that the disease can develop into more severe forms with significant loss of functioning. There is also the danger of mis- or missed diagnosis – a common problem with people thought to suffer from ME.

Providing an incorrect diagnosis, as well as allowing the disease to develop into more severe form, may be fatal – with possible litigation against healthcare providers being a distinct possibility. The continued suffering of people with ME has to be addressed.

THE CHARITY – INVEST in ME

Invest in ME is a UK registered charity which aims to provide better education and awareness about ME. The charity has organised five annual CPD-accredited international biomedical research conferences in London since 2006 – and these have attracted speakers and delegates from over twenty countries from North America, Europe, Asia and Australasia. The charity is also one of the founding members of the European ME Alliance – a group of national patient organisations from (currently) nine European countries which campaigns for biomedical research and more awareness of ME.

After five years of campaigning for awareness and promoting better education about ME/CFS it is felt that the best way to make progress is to establish a national centre of excellence for ME.

THE AIMS and OBJECTIVES

The charity has formed a steering group – the Invest in ME Steering Group (ISG) -consisting of patients and carers from the East Anglian region. This steering group includes Dr. Ian Gibson, former MP for Norwich and former Dean of the School of Biological Sciences at University of East Anglia (UEA), who also produced the Gibson Inquiry – a report by parliamentarians into the state of ME in UK which made a number of major recommendations. Also part of the group is Malcolm Hooper, Emeritus Professor of Medicinal Chemistry at the University of Sunderland. Professor Hooper is the scientific advisor to the Gulf War Veterans group and has extensive experience of studying this condition.

The ISG believe that a change needs to be made in the way service provision for ME patients is carried out and is suggesting a simple but effective structure for providing services and instituting major biomedical research into this disease which will have

ME/CFS Research

A recent study found VP1, RNA and non-cytopathic viruses in the stomach biopsy specimens of CFS/ME patients with chronic abdominal complaints. A significant subset of CFS/ME patients may have a chronic, disseminated, non-cytolytic form of enteroviral infection, which could be diagnosed by stomach biopsy.

For more information:
Chia, JKS, Chia, AY;(2008), "Chronic fatigue syndrome is associated with chronic enteroviral infection of the stomach," Journal of Clinical Pathology 2008;61:43-48.

profound effects on the way ME/CFS is treated in the UK and make Norfolk the hub of scientific and clinical excellence within Europe for ME.

A new commissioning director at Norfolk PCT was recently appointed and is supporting the steering group's views on establishing a research and treatment capacity in Norfolk, which could serve the wider region and the UK and be at the forefront of research into this disease.

THE PROPOSAL

The ISG proposes that a facility should be instigated with four main elements for diagnosis, treatment and research into ME/CFS – service commissioning, service provision with clinical diagnosis and examinations, translational biomedical research and a research database to allow for more research and improved training of healthcare staff.

Figure 1 shows the elements of the model for diagnosis, treatment and biomedical research with patient treatment at the centre of the model.

Service Commissioning

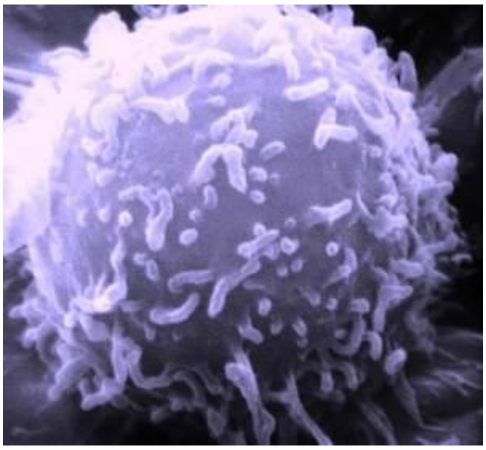
In the proposal Norfolk PCT would commission services directly from Norfolk and Norwich University Hospital (N&NUH) supported by Invest in Myalgic Encephalomyelitis Ltd (a company formed by the charity), if required.

The service would require early diagnosis, examination and treatment of ME/CFS using a clinical biomedical lead consultant with GPs with special interest being connected to the service.

Diagnosis and Clinical Examinations

The examinations of people with ME/CFS would be commissioned by the PCT. Referrals to the N&NUH would be via existing methods from GPs. An important issue is for early diagnosis to be determined.

The service would include a clinical biomedical lead consultant (the charity has already approached possible candidates with the relevant experience) who would perform correct diagnosis (using the international standard Canadian Consensus Guidelines), perform a full examination using a standard clinical protocol and, once patients have been formally diagnosed as having ME, administer possible treatments and participate in biomedical research into the disease.



N&NUH would provide examination rooms, nurses and equipment for these examinations.

This would provide patients and medical professionals with access to specialist assessment, diagnosis and advice on the clinical management, including symptom control and specific interventions. It would also allow provision of specialist advice for more complex cases across the region.

Using a standard diagnostic and clinical protocol, the service would develop a model of care and appropriate care packages for people with severe presentations. It would also establish and co-ordinate a clinical network and disseminate best practice across that network.

Follow-up examinations would be scheduled so that all patients in the region are provided with a service and possible treatments. Results from any treatments would be fed back into a database, to be administered by N&NUH and UEA.

GPs in the area with a special interest in ME would assist and would be trained in the diagnosis and treatment of this condition.

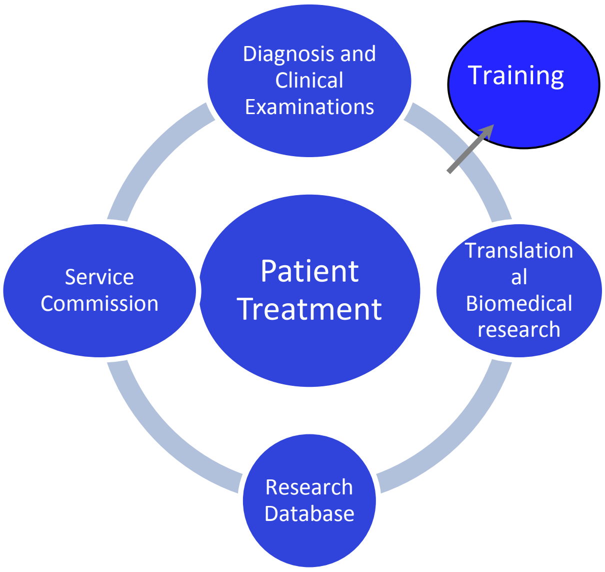


Figure 1 - A Model for Diagnosis, Treatment and Translational Biomedical Research into ME/CFS

UEA - Translational Biomedical Research

The proposal envisages a parallel but complementary element for translational biomedical research to be established at UEA in association with other organisations in the Norwich Research Park.

The idea would be for the UEA to undertake this translational biomedical research using cohorts of patients from those being examined at the N&N hospital and provide possible recommendations for treatment.

The UEA research would be used for more rapid provision of possible treatments for patients whilst at the same time building up the research database for ME/CFS and allowing fostering of new areas of cooperation with other biomedical research facilities.

The research being proposed for the UEA to perform would be of the most advanced possible – using virology and immunology as the key for examining patients. An important aspect of the biomedical research is that properly defined and distinct patient cohorts will be defined and maintained.

This research would be carried out with funding being organised and provided by the charity and other organisations. The research would be oriented toward translational biomedical research, which allows results from research to be applied toward treatments for ME patients.

Initially, the aim would be for the UEA to carry out studies using TGAC's sequencing facility at the Norwich Research Park which would allow all known and unknown viruses present to be identified in a cohort of well defined patients.

Allied to this would be biomedical research projects – the first of which would examine the possible link between ME and gut inflammation which could be performed in cooperation with the Institute for Food Research (IFR).

These initial and ongoing projects would enable a database to be established for use in further research.

A Research Database

A research database will be established which will assist epidemiological studies, enhance research potential and provide patients with proper records of treatment.

A research protocol will be established to outline all the study procedures, including data collection and planned data analysis.

THE CURRENT INFRASTRUCTURE

It is important to stress that this proposal would make use of the existing infrastructure where patients are initially seen by GPs and referred to a consultant.

Where it differs is that a specialist biomedical clinical lead would be used to perform diagnosis and provide treatment and would be working with a translational biomedical research facility at UEA in order to deliver real improvement in patient care from scientific discovery.

THE BENEFITS

The proper examination and treatment benefits patients, their families and the PCT by ensuring that adequate services are provisioned for people suffering from this disease. The hospital and associated staff will be able to be educated in the latest knowledge regarding this disease and would therefore be able to make better decisions. The research carried out with UEA would establish this as the most advanced facility in Europe, thus bring more potential for investment and publicity.

The above proposal would lead to the following benefits –

- early and correct diagnosis of ME/CFS
- the clinical lead consultant would assess and plan the development of future services in conjunction with commissioning PCTs
- it would provide access to specialist assessment, diagnosis and advice on the clinical management, including symptom control and specific interventions, for both patients and health professionals
- eventual provision of an ambulatory service and/or tele-medical services for those severely ill patients who cannot be moved
- development of a network of local multi-agency domiciliary services to support people who are more severely affected and who are unable to access hospital and primary care services
- allow ME/CFS patients (including those severely affected) to participate in clinical trials, where novel research will be conducted, and where medical students can learn about this disease
- facilitate training and education opportunities for healthcare staff to enhance their knowledge and skills in the diagnosis and management of ME/CFS
- lead the development of services within primary and secondary care and support GPs and other health professionals in the care of patients with ME.
- enable healthcare staff to feel more comfortable with the diagnosis of ME/CFS being made
- undertake comprehensive assessments and provide a care package for each patient to include carer and family support
- savings on existing consultant referrals and staff by concentrating ME/CFS examination in one area.

ME Patient Story

“I've been dismissed, ridiculed, had so called medical professionals try to humiliate me.
I've had friends and family turn away from me. I've felt alone, been alone. I've felt depression, frustration, despair and anger at the way I've been treated over many years.

And I've seen how the attitude of the medical profession changes completely when one of their hallowed tests comes back with a 'positive' result.

All it took for me was the great good fortune of finding one doctor who listened to her instincts, that I was genuinely physically ill, and who persevered in trying to find the cause of that illness regardless of how elusive.”

- ME patient (from www.investinme.org)

TRAINING of HEALTHCARE STAFF

The need for training in ME/CFS is one of the main areas of interest for the ISG. The proposed model would allow the GP network to have access to up to date information about ME/CFS including data on treatments and prognosis.

Specialist advice for more complex cases across the country could be provided based on referrals from other PCTs. This in turn would complement the research database thus increasing knowledge and awareness of treatments. Models of care and appropriate care could be developed with packages for people with severe presentations.

FUTURE DEVELOPMENTS

This model would be developed in the future with an ambulatory service and/or tele-medical services being employed for those who are too ill to attend the hospital examination. Phlebotomy services would be provided for home visits to be made to allow the severely affected to participate in the research and allow treatments for these disenfranchised patients.

Additional biomedical research projects by the UEA would increase knowledge about the disease and facilitate development of treatments for patients.

In partnership with the charity more training courses would be arranged with visiting experts (researchers and clinicians) being able to share experiences and data and facilitate more education about the disease.

UK CENTRE of EXCELLENCE in ME/CFS

The ISG proposal, which would aim to involve Norfolk PCT, N&NUH, UEA and ISG, would form the Centre of Excellence for ME which Dr. Gibson and his group of parliamentarians recommended in their Inquiry into ME. The basic model could be developed to assess and plan the development of future services in conjunction with local commissioning PCTs, practice based commissioning organisations and SHAs.

The possibilities allowed for by the combination of N&NUH and UEA and the world-class facilitiesd available in the Norwich research park would provide a focal point in the UK and Europe for training of clinical academic staff in ME/CFS.

Future developments would see the potential of referrals from other areas (and other countries) to be created thus generating income and helping to establish the translational research and treatment facility as the foremost facility in Europe for treating myalgic encephalomyelitis.

CHARITY SUPPORT

The ISG will begin a major national and international fundraising and awareness campaign throughout UK, Europe and the world. The interest from patients, patient groups and other researchers has been extensive.

Invest in ME are supporters of the Whittemore-Peterson Institute (WPI) of Nevada, USA, and have funded UK research by WPI. It has European connections and links to other researchers and institutes in Europe and Australia. The WPI have expressed their support for the charity's efforts in establishing a translational biomedical research base in Norwich and have agreed to cooperate with this. This would allow world-wide publicity for the work being performed in Norwich.

The foundations are therefore already in place to advance science and provide the promise of better treatment and possible restoration of function and lives to a section of the community who have received very little help in the past.

Invest in ME and the Steering group welcome all support to initiate this examination and research facility.

Please support us in helping to treat and provide a cure for ME/CFS.

HOW TO LEARN MORE

Invest in ME have more details available at www.investinme.org .

Email: info@investinme.org

Invest in ME

MYALGIC ENCEPHALOMYELITIS

What is ME/CFS? Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a severe systemic, acquired illness that is defined by the WHO in the ICD-10 code G93.3 as a neurological illness. ME/CFS has clear clinical symptoms which manifest predominantly based on neurological, immunological and endocrinological dysfunction. Epidemiological research suggests that around 240,000 people in the UK have ME/CFS (five times more prevalent than HIV/AIDS). As many as 25,000 are children and adolescents. Onset commonly occurs during the 20s to 40s in adults, and between 11 and 14years in children.

What are the symptoms of ME/CFS? The varying symptoms experienced by many severe ME sufferers include: -
post-exertional malaise and loss of muscle power with delayed and prolonged recovery, general chronic weakness of limbs, neurological disturbances, cognitive problems such as memory loss & concentration difficulties, problems with balance and fine motor control, muscle pain, malaise, hypersensitivity, sleep & temperature disturbance, cardiovascular symptoms, digestive disturbances, visual problems, vocal/muscular limitations. (http://www.euro-me.org/news-Q42008-001.htm)

What is the cause of ME/CFS? ME/CFS frequently follows an acute prodromal infection, varying from upper respiratory infections, bronchitis or sinusitis, or gastroenteritis, or an acute “flu-like” illness. While the pathogenesis is suggested to be multi-factorial, the hypothesis of initiation by a viral infection has been prominent. A wide range of viruses and other infectious agents, such as Epstein-Barr Virus, Human Herpesvirus-6 and 7, Enterovirus, Cytomegalovirus, Lentivirus, Chlamydia and Mycoplasma have been investigated. Before acquiring the illness most patients were healthy, leading full and active lifestyles. Biomedical research has provided evidence of distinct subgroups within ME/CFS.

Recent research by the Whittemore-Peterson Institute, the National Cancer Institute and the Cleveland Clinic of USA has linked ME/CFS with the presence of a newly discovered retrovirus. Studying peripheral blood mononuclear cells (PBMCs) from ME/CFS patients identified DNA from a human gammaretrovirus, xenotropic murine leukemia virus-related virus (XMRV), in 68 of 101 patients (67%) compared to 8 of 218 (3.7%) healthy controls. (http://tinyurl.com/ykxx9jn **).**

How is ME/CFS diagnosed? The most effective and accurate method is via usage of the Canadian Consensus Criteria. Often ME/CFS is diagnosed by the exclusion of other conditions that resemble ME/CFS.

Are There Any Treatments for ME/CFS? There is no one specific treatment for ME/CFS but biomedical research has identified a number of interventions which have been found to be beneficial.

What is the likely outcome for someone with ME/CFS? Prognosis varies and depends on factors such as age, time of diagnosis and treatments. In a review study of prognosis[7], 5 of 6 studies indicated that 0% to 6% (the sixth study indicated 12%) of adults return to their pre-illness level of functioning. Relapses can occur several years after remission. The prognosis for children and youth may be better but the condition can have serious effect on their development. Symptom severity is the best indicator of outcome, but accurate prognosis for an individual cannot be predicted with certainty.

ME/CFS in Children Children of any age can develop ME/CFS, often with an acute infective onset. The main symptoms are similar to those seen in adults but children with ME/CFS may have additional symptoms such as abdominal pain, nausea, and sinus congestion. As many as 25,000 ME patients are children and adolescents.

More information available in the Canadian Consensus Document - **http://tinyurl.com/caka2w**