

INTACT

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MARIE CURIE ACTIONS
Research Training Networks (RTNs)

INTACT

Individually Tailored Stepped Care for Women with Eating Disorders

PARTNER LIST

Participant number	Participant Organisation legal name and Department	Country
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3	Charles University Prague First Medical Faculty, Department of Psychiatry	CZ
4	Institute of Psychiatry London, Eating Disorders Research Unit	GB
5	Semmelweis University Budapest, Institute of Behavioural Sciences	HUN
6	Universidade do Minho, Braga, Departamento de Psicologica	P
7	University Medical Center Utrecht, Rudolf Magnus Institute of Neuroscience	NL
8	University Hospital of Geneva, Service d'enseignement thérapeutique pour maladies chroniques	CH
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B1 SCIENTIFIC QUALITY OF THE PROJECT

B1.1 Research topic

The INTACT network will research and develop innovative strategies for the optimisation of health care in the prevention and treatment of eating disorders (ED). ED such as anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorders (BED) are serious and complex disorders affecting mainly female adolescents and young women. They are relatively common in industrialised societies and are rapidly increasing in economically emerging regions. More than one million young women (plus a considerable but unknown number of girls and female adolescents) were affected by these eating disorders within the past 12 months¹. ED are associated with an elevated risk for physical disability and psychiatric disorders, and especially for AN with a high mortality. Self-harm such as cutting and burning oneself are common, and a high risk for co-morbid substance misuse disorders is also present (e.g. [1], [2]). BED are often associated with obesity, which is becoming the next public health epidemic [3].

Treatment is costly, and not always successful. This is especially true for AN which has the highest average cost by diagnosis of any psychiatric condition ([4], [5]). Various treatments proved efficacious [6], however the situation is far from satisfactory. In a European collaboration data were collected from 3284 patients at 80 centres in 14 countries yielding the following findings [7]:

- Many patients get help late: the mean illness duration was 6.6 years,
- Effectiveness of treatment is low: only 31 % were free of the key symptoms after treatment,
- Risk of relapse was high: after 1 year approximately 40 % had relapsed,
- The effectiveness varied considerably between the centres and in many places was considerably lower than that achieved under experimental conditions.

Research of the last decades led to a better understanding of ED. Several studies give hope for effective treatment. *Individually tailored strategies*, that include early intervention, treatment, and after care measures and a *stepped care* approach, in which treatments are provided sequentially according to patients' needs, have been recommended (e.g., [4]). However, research into these approaches is still in its infancy.

The INTACT network believes that the development of individually tailored, stepped care treatment approaches for ED begins with a better understanding of the processes of getting ill, getting well, and staying well, and that these treatments can be enabled and delivered cost effectively by the use of Internet and mobile technologies. The focus of INTACT will lay the scientific foundations for these innovations and will tackle methodological and technological challenges by focusing on three major themes:

- (1) Research on the risks for the development of an ED and the identification of the individual resources that are crucial for recovery. INTACT will develop longitudinal risk models to identify genetic, environmental, and psychosocial factors that further or hinder the development of an ED and process models of the course of recovery. The network will also study the impact of media on at risk populations, i.e. teenage girls, and young women. A better understanding of this influence, at the psycho-linguistic level, will help improve future prevention and treatment strategies for ED.
- (2) Understanding the process of getting ill, getting well and staying well in order to support the development of new methods, and strategies for (1) individual tailored care, according to the needs and resources of the person, and (2) the provision of seamless care from prevention to treatment, and through to post-treatment care.

¹ Green Paper: Improving the mental health of the population: Towards a strategy on mental health for the European Union, COM(2005)484, 14.10.2005.

(3) Explore the potential of the latest communication tools such as Internet and mobile phones to develop tools for clinical knowledge management and to enable the delivery of innovative step care programs for eating disorders (e-health).

These tasks call for collaboration of researchers, clinicians, and technicians, of specialists from psychiatry & psychology, genetics & biology, informatics & computer linguistic, public health & economics. The major activity of the network is to train young and experienced researchers in working with the latest investigation tools and models for fundamental research into the aetiology of ED, as well as, applied techniques in developing clinical evidence for the deployment of new “technology enabled” prevention or treatment strategies. Thus, this network will provide an interdisciplinary environment that offers opportunities for training and research in new fields, bridging boundaries between academic, and innovative small enterprises (SMEs).

B1.2 Scientific originality of the project

This RTN is motivated by the lessons learnt from the data of more than 3000 patients within the European collaboration COST Action B6 (co-ordinated by the Heidelberg group), two Framework V projects “Factors in Healthy Eating” (co-ordinated by the London group), which focussed on genes and environment in ED, and SALUT: Intelligent Environments for the Diagnostic, Prevention and Treatment of Eating Disorders (co-ordinated by the Swiss group) focusing on the development of web based tools and strategies for the treatment of ED. The combined results of these projects will set the foundation for originality and innovation within the INTACT network.

INTACT will innovate by developing individually tailored treatment and stepped care interventions based on research into the process of getting ill, getting well and staying well. Not all women at risk for ED actually develop the disorder and not all of those who fall ill need the same type and intensity of care. Some may be helped through information or psycho-education by working with a self-help book or interactive computer programme, others may benefit from support through friends, relatives or paraprofessionals, and again others may require long-term treatment from a professional therapist with specialised expertise. When in treatment, some respond quickly, others slowly or not at all.

Research into the process of getting ill will be used to develop prevention and early intervention strategies (step-up), research into the process of getting well will support the development of individually tailored treatment strategies, and research into the process of staying well will inform innovations in relapse prevention and treatment aftercare (step-down). Developing a *stepped care* approach, in which treatments are provided sequentially according to patients’ needs, will be a significant innovation of the network.

Another INTACT innovation is looking at chronic disease management as a process continuum rather than as discrete steps towards wellness. Up to now, research has concentrated on the search for and evaluation of efficacious treatment. Scientific knowledge about steps of care before regular treatment is meagre, and almost non-existent for steps of care after regular treatment. INTACT will give priority to understanding step-up and step-down care, as well as, exploring the links between the steps, i.e. when does treatment stop and aftercare begin.

Finally, the INTACT network includes European researchers that are at the leading edge of risk factor research, especially, gene-environment interaction and psycho-linguistic. Another strength of this network is the integration of two European partners (a research institution and a SME) that are pioneers in the use of evidence based SMS and web based therapeutic support and aftercare programs for patients with mental disorders. Thus, INTACT will help create a critical synergy between these pioneering groups and help reinforce and maintain European leadership in the development of more accessible and cost effective e-health programs for ED.

B1.3 Project objectives

The overall objective of this RTN is to improve our knowledge about how to provide optimal care for people at risk of or suffering from ED, thus, specifically contributing to improving quality of life of young women. The network seeks to provide a multi-sectorial and multi-disciplinary training ground for young and experienced researchers by providing the opportunity to research and develop new cost effective, patient centred health care delivery strategies required for meeting the challenge of providing quality health care. Specifically, INTACT will conduct research on the process of getting ill, getting well, and staying well, and will help describe a strategy for the optimisation of costly resources allocation in health care and, at the same time, to optimise of the match between patients' needs with the type, intensity and duration of care. This research is organised into the following objectives:

1. Prevention & early intervention (step up care): The applicants see three research priorities:

1. To improve scientific knowledge about the process of getting ill: Although cross-sectional studies generated useful hypotheses regarding risk factors [8], longitudinal data are required now to determine whether these putative risk factors actually precede the development of an ED. INTACT will prospectively monitor the course of mental health of adolescents and young women at risk over critical periods of up to two years focussing on the putative risk factors such as drive for thinness or adherence to perfectionist standards for anorectic symptoms or negative affect for the binge-purge cycle [9]. Linguistic fingerprints [10] will be looked at to better understand the role of media. The data will be integrated with genetic risk factors as they emerge, to create a gene-environment model of ED [11].

2. To develop and evaluate innovative e-health tools for prevention: According to recent research and own experience the delivery through the internet or other new media appears helpful for bringing care to the people who need it (e.g., [9], [12], [13], [14]). Therefore, INTACT will give the development and evaluation of such e-health tools special attention.

3. To bridge the gap between available help and individual needs especially for under-served groups: There are strong suggestions that women from ethnic, cultural or religious minorities who have ED are under-diagnosed and go untreated [15]. The RTN will investigate the relationship between epidemiological assessed need for mental health care and subjective perception of need of young minority women and/or their parents [16] and use this new knowledge to improve care for these groups.

2. Individually tailored treatment: For BN and BED cognitive behavioural therapy (CBT) has consistently been found to have reasonable efficacy (e.g., [6]). However, only 40% to 60% of patients treated with CBT cease binge eating and purging completely, some show partial improvement, but a number derive no benefit at all [17]. Recent research suggests additional steps of care to enhance the effectiveness of CBT [18]. The situation is worse for AN. There is very little evidence to guide decisions about which form of clinical management or type of therapy to choose, and no effective drug treatments. The clinical literature usually suggests inpatient care ([19], [4]). This implies a considerable financial burden for families and health care systems and underpins the need for new, more effective, but less costly and intrusive strategies of care. The role of the family in treatment is often emphasised for AN. That invites research for innovative ways of involving families and parents [20].

INTACT sees two ways of improving efficacy, effectiveness, and cost-efficiency of treatments:

1. A better understanding of the processes of getting well: Surprisingly little is known about how e.g. CBT, the best researched therapy, achieves its effects. Only recently, this issue has been addressed [21]. Almost nothing is known about (e.g.) whether and when significant changes in behaviour occur and how these interact with changes in attitudes and what specific patterns of change may mean for final outcome. INTACT will use the monitoring system web-AKQUASI ([22], [23]) developed by the Heidelberg team that allows such innovative process-outcome research.

2. *Adaptive treatment strategies*: Patients respond differently to therapy. Some respond rapidly, others slowly or not at all [21]. New findings suggest that timely feedback on individual response to the therapist can be used to adapt the interventions to the individual speed of change and thus, enhance treatment outcome ([23], [24]). Again, the use of systems like web-AKQUASI will allow the RTN to systematically evaluate such strategies.

3. Relapse prevention and rehabilitation (step-down care): Patients who do not respond to the best available treatments or relapse soon after end of treatment present a major challenge. INTACT sees two key strategies for improving their care:

1. *Post-treatment care for non-responders through e-health*: Only one study so far has addressed this problem in ED [25]. Patients with BN who did not sufficiently improve at the end of a CBT package received either a course of interpersonal psychotherapy or medication. About 50% of the patients dropped out of the second-level treatments. Data of COST Action B6 suggest to give slow responders more time and treat rapid responders more briefly. INTACT will investigate such individually tailored treatment duration as an alternative to the application of rigid second-level treatment.

2. *Post-treatment relapse prevention*: Relapse after successful treatment is quite common in ED, relapse rates go up to almost 50% within 6 months after treatment ([7], [26]).

The RTN sees great potential for e-health to enable individually tailored post-treatment care. This relies on positive experiences of members of this RTN. A minimal support programme delivered through text messaging yielded promising results. It proved technically feasible, highly acceptable to patients with BN, and cost-efficient [13].

Patients with AN need more intensive after care. They often leave hospital in a state of partial remission only. The RTN will investigate the effectiveness of a continuation treatment via the Internet; i.e., patients will be transferred to group-therapy that will take place in an Internet chat-room as successfully piloted by the co-ordinating network team [12]. Parents will be invited to participate in internet-self help groups while their children are treated in specialised hospitals [20].

B1.4 Research method

INTACT will offer training opportunities in non-standard research methods and novel applications of modern technologies for an innovative care model for women with ED. Especially, INTACT will enter uncharted territory in the following areas:

Genetics and biology: The new possibilities of genetics open an exciting avenue for ED research. Participants in this network have been pioneers in the application of genetic and biological research to better understand the aetiology of ED (especially in the FP5 project “Factors in Healthy Eating”). This information can also be used, in nosological classification of a complex and fluid diagnosis and in treatment choices.

The identification of genetic risk factors for ED, and the focus on genetic endophenotypes such as childhood perfectionism and measures of drive for thinness, rigidity and persistence are possible important tools for advancing the care of patients with ED. These genetic factors may influence not only the onset of illness, allowing us to identify high risk individuals but also the course and outcome. As an example, the planned prospective study of patients in treatment will allow us to identify the genotypes of those who do best at a particular type of therapy such as CBT, as well as other vulnerabilities such as obsessive compulsive behaviours which can be specifically addressed.

Linguistics: The use of new communication technologies in psychotherapy (e-mental health) opens not only ways for innovative forms of delivery of care, but also promises new insights in mental illnesses through the investigation of patients’ language and communication styles (“linguistic fingerprints”). The field of Computational Linguistics made tremendous progress in the last ten

years. Robust text analysis tools have been made available which opens up attractive innovative applications of natural language processing techniques in ED research.

Society and culture are assumed to have an immense influence on eating behaviour. From an anthropological and sociological perspective, it is postulated that the risk for ED is increased by a cultural pressure, which emphasizes thinness as a socially important value. Socio-cultural values and attitudes such as the unrealistic standards of female beauty are to a substantial extent transmitted through the media (e.g. advertising and promotional materials). It is hypothesized that adolescents at risk for the development of ED display a specific responsiveness to such media messages. Analysing both, the language of young women with different cultural backgrounds, and media contents in different societies (e.g. newspapers, women's magazines) on multiple linguistic levels, allows the investigation of this assumption and promises a better understanding to which extent ED are "societally induced".

Delivery of care via Internet and mobile phones (e-mental health): Secure data transfer and management and protection of privacy are essential for the use of modern communication means in health care. The methodologies briefly described below have been examined and approved by ethical committees in Spain, Sweden, France, Germany, and Switzerland as well as by the official representative of the office for data security of the state of Baden-Württemberg (D). NetUnion will bring in the specific expertise in security techniques and software programming for safe and confidential use of Internet and mobile phones.

Members of this network were among the pioneers in the use of modern communication technologies for the delivery of care for patients with mental disorders. They successfully piloted various approaches, which proved technically feasible, highly acceptable to the patients, helpful, and cost-efficient ([12] [13] [14]). INTACT will evaluate three most promising adaptations:

Online treatment support and relapse prevention for BN and BED: The online therapeutic support programme for BN from the SALUT project will be adapted for the purpose of individually tailored treatment support and relapse prevention for BN and BED.

Post-treatment care through computer mediated text messaging via mobile telephones: After the end of treatment patients with BN send weekly-standardised reports on the status of their key eating disorder symptoms. A computer programme evaluates the patient's current status in comparison to the preceding one and suggests one-response statements out of a set of pre-prepared alternatives, that reinforce improvement and suggest alternative behaviour in case of deterioration. A person with basic clinical training checks its suitability for this individual patient before sending it.

Post-treatment care through internet chat-groups: After the end of treatment patients meet as a group in an internet chat-room together with a clinically trained moderator. The setting is kept similar to typical group therapy sessions; i.e. 8-10 patients meet weekly for 90 minutes for a maximum of 52 weeks. In the opinion of the RTN this approach is suited for patients with AN, who are often treated in specialised hospitals far away from the home of the families – not at last, because family members can easily be integrated via the internet.

Assessment technology and statistical methods: The consortium of the RTN considers information to be the key to individually tailored stepped care. As the clinical decisions about continuation of a specific step of care or switch to another depend on the actual information about the current individual status of the patient, the availability of useful information at the right time is central. Web-AKQUASI, a specifically developed software for the documentation, evaluation, and information feedback of care for patients with mental disorders will be used for monitoring status, progress and treatment outcome of patients. Web-AKQUASI was developed by the co-ordinating network team. The basic version has been used in several thousand cases and has proved practical and useful in clinical routine ([22]). The newest version uses internet-technology and is prepared for

decision oriented testing, which promises to significantly reduce the time and effort of the assessment without loss for the quality of the decision [23].

The use of the web-AKQUASI will optimise communication within the participating network teams (intra-net) as well as between them (Internet) in various ways: (1) It supports data entry by hand, by scanner or electronically by PC, handheld computers. (2) It standardises the structure of the data base across the various participating network teams. Although it will be possible to add measures which are of specific interest to a network team, the standardised structure will ensure data compatibility and ultimately efficient data exchange between the network teams. (3) It transforms the incoming data into meaningful information, i.e. in the given context, into standardised information on current status and course of health. (4) It provides specifically developed feedback tools that transport the information to the interested parties.

In terms of assessment measures, INTACT takes advantage of the procedures for clinical diagnoses, and psychometric questionnaires that have been standardised and validated in the COST Action B6 [7]. The instruments capture the view of the clinical experts as well as the view of the patients and people at risk. The main instrument for the clinical assessment is the Longitudinal Interval Follow-Up Evaluation (LIFE). This includes standardised procedures for diagnosing ED according to DSM-IV, a standardised rating scale for severity (psychiatric rating scale), and a measure for the assessment of co-morbidity and general functioning [27]. The self-report measures allow patients to give their own view on their health status and problems. They comprise ED specific instruments as well as instruments for the measurement of general psychological impairment.

Expected breakthrough: We expect a major breakthrough in the optimisation of care for young women at risk for or suffering from ED through the new knowledge and technology created in this RTN. Specifically, we envisage:

- (1) better understanding of the gene-environment interaction and its use for creating targeted prevention and maintenance programmes.
- (2) better understanding of the influence of media and cultural differences on the development of young women through linguistic fingerprints.
- (3) easier access to effective care for people who are under-served today, e.g., people in rural areas, and cultural or social minorities.
- (4) more effective delivery of care through the use of modern communication tools such as Internet and text messaging.
- (5) greater cost-efficiency through individually tailored stepped care that will better allocate expensive therapeutic resources according to the individual's needs.

B1.5 Work plan

The work programme consists of 14 innovative studies and is divided into four work packages (WP). In addition to the description below, the studies and the responsibilities are displayed in table 5 (p.37). Each of the network teams takes full scientific responsibility for the studies that it is conducting. The studies are actually carried out in public or private clinics, i.e., under 'real life' conditions in non-academic routine. They are inter-connected through the general topic and objectives. Tables 1 and 2 give an overview on the work and time plan and the deliverables of the RTN.

The co-ordinating network team together with NetUnion will serve as the technological support centre and will provide the tools for assessment as well as for the computer mediated communication (e-health) and be responsible for the envisaged adaptation to future methodological and technological developments. Specifically, the co-ordinating centre in Heidelberg will be responsible for the data management and statistical analysis according to the standards of the

International Harmonisation Conference (especially ICH E6² and ICH E9³), while the adaptation of the e-health tools, provision and technical support for their use will be concentrated in Lausanne (NetUnion).

The work packages are connected as depicted in figure 1 and the work will be co-ordinated to maximise synergy (e.g. by sharing the e-health tools such as assessment technology, computer mediated communication) and thus facilitate training visits and secondments.

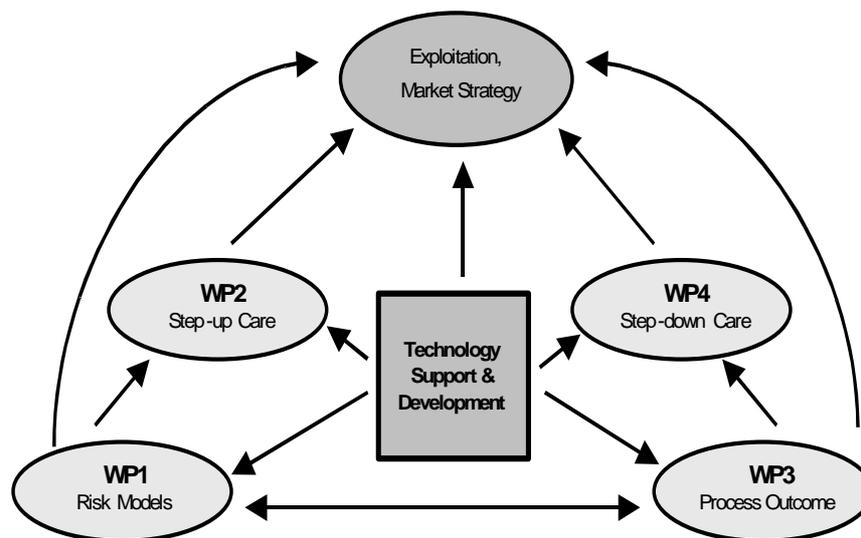


Figure 1: Thematic and organisational structure of the work programme

Research into the modelling of psychological risk factors (2 studies) and of therapy process and outcome (5 studies) will use a similar experimental design (prospective longitudinal observational studies) and statistical methods (such as discrete time survival analysis and hierarchical linear modelling). Both types of studies will also aim to identify patterns or sequences of change (e. g. investigating whether change of one factor depends on the change of another).

The genetic and linguistic part of the research programme go across several studies of the RTN. The genetic approach requires specific knowledge and infrastructure (provided by the London and Utrecht groups). It may be particularly powerful for integrating genetics into the assessment of risk factors (e.g. by gene-environment interaction; WP 1), and contribute to the optimisation of treatment by identifying genetic factors relevant to early onset cases (WP 2 & 3). To obtain DNA, cheek swab samples will be taken from consenting participants at all sites and sent to London for preparation of DNA and analysis of genetic information by standard methods. Members of the RTN will be trained in the use of this genetic data in the types of analyses envisaged in the work packages. The network team in London will co-ordinate this part of the research programme and ensure the specific methodological standards. The linguistic part of the research programme will also use data from several studies of the RTN. Besides the study on the writing style of female adolescents in Germany, text material will also be automatically collected via web-AKQUASI in the other two studies on risk factors for the development of ED.

² Good clinical practice. London, UK: International Conference on Harmonisation, 1996. Adopted by CPMP July 1996 (CPMP/ICH/135/95).

³ Statistical principles for clinical trials. Good clinical practice. London, UK: International Conference on Harmonisation, 1998. Adopted by CPMP March 1998 (CPMP/ICH/363/96).

The specific step-up (2 studies) and step-down care approaches (3 studies) will build on the process models mentioned above. These intervention studies will share the same experimental design (randomised control trials using the adaptive randomisation strategy) and will use similar statistical methods for the evaluation of the efficacy. The accompanying process studies will investigate how individual tailoring – that is, the continuous flow of information about the process of change – affects the clinical decision-making and eventually the change process itself. These process studies can be considered as empirical validation of the ones developed in the first step and may lead to their modification.

WP 1: Development of risk models (studies 1-4):

Four studies aim to develop risk models to improve knowledge about how people develop ED. Given that ED are complex and multi-faceted phenomena, INTACT investigates risk factors from a psychological, biological, and socio-cultural perspective.

The teams in St. Etienne and Braga will specially focus on under-diagnosed and/or under-treated groups. While the French team will examine the impact of acculturation on help seeking behaviour (especially in people of North-African origin who are common in the Rhone-Alpes area) and on the risk for developing an ED, the team from North-Portugal will focus on the rural population in the Minho region around Braga. Both studies will be based on adequately powered sample sizes of about 1000 women for the screening and then appropriately specified for the specific research questions of the further stages.

Co-ordinated with these two studies on psychological risk factors, the team in London will examine the impact of genetic risk factors on the development and course of ED. The identification of genetic risk factors for ED is making rapid progress through the efforts of researchers at the NIMH and in Europe (EC Framework V QLK1-1999-00916). Emerging genetic risk factors include the brain derived neurotrophic factor in ED (BDNF), genetic factors related to obesity in bulimic illness, and genes of the serotonin and dopamine systems in personality and psychopathology factors such as harm avoidance, obsessive compulsives and perfectionist traits. We do not intend to identify risk genes in the present study, but to use risk genes identified by other large and powerful studies such as those currently underway in the USA and Europe.

Investigating the role of the mass media in the development of ED and especially addressing the question to which extent language reflects an increased risk for ED, the team in Heidelberg will investigate the linguistic style of female adolescents in different age groups, and with different cultural backgrounds (“linguistic fingerprints”). Data will be collected from German adolescents as well as from women participating in the studies on psychological risk factors conducted by the teams in Braga and St. Etienne.

WP 2: Longitudinal risk models & step-up care for early intervention (studies 5-6):

The expected findings of WP1, i.e. the identification of sub-syndromal and full ED cases will be used to develop and evaluate a low intensity intervention for young women who present with mild to moderate symptoms. The approach will comprise a comprehensive clinical assessment combined with a small number of psycho-educational sessions succeeded by a low intensity long-term support. The latter will consist of a computer assisted reinforcing supportive programme that uses text messaging via mobile telephones.

Variants of the programme will be developed to address the specific needs of providing care in a rural area like North-Portugal or to facilitate access to care for young women of North-African origin in the Rhone-Alpes area: In the Braga study, there will be monthly visits to a primary care physician. This inclusion of ‘sentinel’ doctors will address the problem of under-served groups in

the rural north of Portugal. Continuous monitoring will be used to individually tailor to decide when to discontinue treatment of responders and when to refer to specialist care at the co-operating clinical centres in case of non-response or deterioration. The team in St. Etienne will adapt the programme for use in their centre. Additionally they will develop and evaluate a culture-specific version of the intervention for female students of North-African origin who subscribe at the Universities of St. Etienne and Clermont-Ferrand.

WP 3: Development of longitudinal therapy process-outcome models (studies 7-11):

So far, little is known about the processes of improvement in psychological treatment for ED. A better understanding of these processes, especially of rapid response and slow or non-response to treatment, is crucial for individually tailored care. Therefore, longitudinal prognostic studies (LPS) will be conducted for patients with AN, BN, and BED to develop process-outcome models.

The team in Budapest will focus on BN, and the team in Geneva on BED. The teams in Prague and London will conduct a two-site LPS on AN to ensure an appropriate sample size.

The team in Utrecht will conduct a third study on AN, focusing on the relation between biological mechanisms and treatment process and outcome in adolescent patients. There is empirical evidence that AN and the onset of puberty might be related and that certain neuroendocrinological profiles are related to outcome in AN patients. Mainly the Leptin level seems to be a good indicator for a patient's current status. Therefore the team in Utrecht will add genetic and repeated neuroendocrinological assessments to the design of the AN studies described above and investigate the relevance and prognostic value of these information for events such as treatment response, non-response and outcome.

WP 4: Enhancing the process of getting well through step-down care (studies 12-14):

The models developed in WP 3 will provide information on when key improvements are achieved. Randomised controlled trials - separate for AN and BN - will evaluate the efficacy and cost-effectiveness of two different step-down interventions.

All studies will start with "treatment as usual" followed by a low intensity step through computer mediated communication: a) The team in Budapest will investigate how care for BN patients can be improved when CBT delivered in an outpatient setting is followed by a computer-assisted text messaging approach via mobile telephones. b) For AN, at both sites (London and Prague), the initial treatment will be inpatient therapy followed by an aftercare programme which will be provided through Internet chat-groups led by clinical moderators for about six months.

Given the broad agreement that parents or families should be included in treatment of AN, the two network teams will carry out complementary research into different ways of involving carers: Whilst the team in London will investigate the effects of an interactive Internet-based carer training programme, the team in Prague will offer multifamily group sessions through Internet chat-rooms.

B2 TRAINING AND TRANSFER OF KNOWLEDGE ACTIVITIES

B2.1 Objectives

The overall objective of this RTN is to maintain and advance European leadership in the research and deployment of innovative health care model and services for women with eating disorders. The network addresses in a timely fashion, an important knowledge gap in the quest for developing individually tailored stepped care models, and answers an urgent need for a focused and highly visible European platform to train and retain a critical mass of young researchers to sustain the capacity and competence of European research for better health care solutions, especially in the fast growing area of e-health.

INTACT will bring together researchers, clinicians, and IT professionals to create a interdisciplinary and inter-sectorial network of academic and non-academic partners, with complementary knowledge and skill sets. The training programme is designed to take full advantage of this diversity, by offering young and experienced researchers the opportunities to work with world-renowned researchers in their area of expertise (i.e., genetic analyses, linguistic analyses, longitudinal methods, e-health programmes, stepped care). They will also receive practical training, acquiring the necessary complementary skills to increase career mobility and development (e.g. ethics, data protection, project management, publication, dissemination, market strategy).

The assembled network has a European, as well as, an international dimension, that cannot be duplicated in any national setting. Starting from a core group of pioneering institution, INTACT seeks to become the reference network for European e-health research, training and technology transfer in tailored stepped care and e-health for eating disorders. This ambition is supported by a clear strategy for dissemination, technology transfer, and collaboration with other European and international research networks, as well as partners from newly associated states and less advantaged economic regions in Europe. (See technology transfer and dissemination strategy in section B4).

At the same time, INTACT will further support the need to **reduce fragmentation in European research and training**. The network has already taken first steps by including partners from less favoured economic regions and newly associated members states, i.e. Northern Portugal, Hungary and the Czech Republic, and by consolidating key members of 3 previous European research consortium on eating disorders (COST Action B6, FP 5 projects "Factors in Healthy Eating", and "SALUT": Intelligent environments for the diagnostic, prevention and treatment of eating disorders) into one focused research and training network.

B2.2 Requested personal resources

The applicants consider essential for the training and career plan of the early stage researchers (ESR) that they fully share scientific responsibility in a study. Therefore, we envisage that one ESR will always conduct one of the 14 studies as principal co-investigator supervised by a personally assigned experienced senior researcher from the host team. Specifically, the ESR will be involved in the development of the design, collection of data, statistical analysis, and publication. Therefore, the contract with the ESR should cover the whole study period. The requested total of 468 person-months of ESR follows from the duration and work programmes of the 14 studies (see table 5, p.37).

The situation for the more technically oriented ESR and the three ER is slightly different (see p.38). Especially the three ER will be essential for the transfer of the technological knowledge in this project. Therefore the ER will be employed by the Heidelberg team and NetUnion. The adaptation and further development of the e-health tools require researchers with sound experience in psychometrics, informatics, and software engineering. At the same time the work planned is innovative and will be of great value for the future career of the ER. The knowledge transfer to the

specific study groups will be needed for the whole duration of the RTN, which justifies the requested 66 person-months for three ER. The recruitment plan is outlined in detail in B4.3 (table 5, pp.37-38).

B2.3 ESR and ER Career Development Plan

The specific studies planned are novel and challenging, and offer opportunities for training in new concepts, methodology, and technology. We are confident that ESR can accomplish the work under supervision of experts and in co-operation with other post-doctoral and doctoral students at the sites.

Each ESR and ER will be assigned to a mentor, who will advise her or him on setting up a personal career development plan. Especially, ESR will be encouraged to use the studies that are assigned to them as a dissertation (because the different conditions across European countries, this cannot be mandatory). For the ERs, greater emphasis will be put on continuing education and career planning. Working together with the experts of NetUnion will further the specialisation of the ER, and the co-operation with the teams conducting specific studies will further the interdisciplinary orientation.

B2.4 Training resources of the network teams

All research teams of the network are associated to universities. This ensures free access to all academic facilities, lectures, and seminars for the ESR that will be essential for their research and training (see also B3.2). Sequential employment through NetUnion and the Centre in Heidelberg and secondments will ensure full access to academic training and exchange for the ER. All network teams are co-ordinated by nationally and internationally highly respected researchers. The ESR and ER will be fully integrated into the teams comprising post-doctoral researchers and doctoral-students working in this area.

B2.5 Specific training and transfer of knowledge

The project aims require interdisciplinary and inter-sectorial co-operation. The training on network level will comprise training in and knowledge transfer of a broad range of specific contents such as:

Research and Methodology:

- designs for molecular genetic analysis of disease course, treatment response and endophenotype analysis such as factors influencing personality and neuropsychological impairment
- evaluation of the function of genetic risk factors and their interaction with environmental factors
- public health research: a) research into under-diagnosed and under-served groups such as ethnic, cultural or religious minorities, migrants, or rural populations; b) relevance of cultural and sociological factors for ED research; c) health economics
- automatic text-analysis on different linguistic levels (“linguistic fingerprints”)
- individually tailored interventions, flexible treatment strategies, stepped care
- development and application of e-health tools for the effective delivery of care
- computer-assisted assessment and clinical knowledge management
- non-standard methodology and statistics (e.g. longitudinal analyses, stochastic modelling to better understand the processes of getting ill and getting well)
- data security and privacy protection for online health information

Complementary skills (foreseen co-ordinating experts in brackets):

- ethics in research under special consideration of e-health programmes

- communication with the scientific community: writing, presentation, and publication
- communication with the non-academic community especially: patient and carer organisation as well as general public
- project management, grant writing, financial planning and resource management
- implementation of programmes into routine care and into clinical education programmes
- cost-benefit analysis, market segmentation and market strategies.

In sum, the training programme covers a broad range of general contents relevant for research (e.g. ethics, data protection, project management, publication, dissemination, market strategy) and of specific topics relevant for the INTACT network (e.g. genetic analyses, linguistic analyses, longitudinal methods, e-health programmes, stepped care). Thus ESR and ER will acquire a variety of complementary skills and knowledge for their concrete work in the RTN but also for their future research career.

B2.6 Training

INTACT combines local and network-wide training activities. Training will be offered on an individual as well as on network level. The intensive use of Internet communication bridges training on individual and network level, so that roughly a ratio of 40% to 60% is envisaged.

Individual training is provided by the host institution and includes the facilities and training programmes of the universities. Taking over the responsibility for the foreseen study, supervised by an experienced team member will be an essential part of the individual training. The personally assigned mentor of the host network team or another partner of the RTN will support the development of individual training plans on a day-to-day basis. Both, the ESR and ER will be fully integrated to the team and participate and contribute to the team conferences and seminars. Special support will be provided to facilitate the start, e.g.:

- English will be the official language within the network. However, in all specific studies interaction with probands or patients will be required. Therefore - if necessary - a 4 week language course will precede research activities whereas training can start following arrival.
- Guest researchers will receive assistance in finding housing, either by taking advantage of existing structures such as University owned guest houses or on a private basis. Special attention is given to the needs of women by providing housing in safe neighbourhoods.
- Working hours and working arrangement for parents caring for young children can be flexible.
- In several of the centres support for foreign researchers is provided on an University level – researchers in INTACT will receive the respective information. Thus, social integration of the researchers into the host culture will be explicitly fostered.

The ESR will be encouraged to visit and participate in parallel studies at other places, most typically in form of secondments. Sequential employment and secondments of the ER through NetUnion and the centre in Heidelberg as well as research visits of the ER at the various study sites to transfer the knowledge to the teams responsible for the specific studies are indispensable.

Training at network level comprises seminars, summer schools, workshops and symposia that the RTN will conduct at varying places. Responsibility for these training activities will be distributed equally among the network partners and according to their main research expertise. The foreseen network teams responsible for the organisation are listed in table 3. The technology of secure and confidential Internet chat will be adapted for the purpose of teaching and training which will allow scheduling weekly seminars via Internet. That means, presentations and lectures relevant to status and progress of the specific studies will be delivered through the Internet and discussions will be arranged in a chat-room. The use of Jabber-Technology (which provides electronic tools for e.g. instant messaging, virtual collaborative working, a remote system, the common use of data files, secure data transfer between users) will considerably facilitate the co-operation between the trainees at the different sites.

Basic Training: The recruitment of ESR will be run in two main waves with a time lag of 12 months. This will allow the ESR of the first wave to contribute substantially to the training of those in the second wave. For both groups a one-week training seminar will be organised within 3 months after start of recruitment to introduce them to the specific study they are recruited for. This training comprises basic knowledge about ED and ED treatment as well as the methodology for designing and conducting the study. The seminar will be followed by a workshop to bring the ESR together with the network teams, to co-ordinate the start of the studies, and establish personal contacts.

Workshops & Seminars: Usually, two workshops accompanied by training seminars will be conducted per year (see table 3). The workshops and training seminars will bring the ESR and ER together with researchers of the network. Participation will be open for post graduates of the network teams not appointed through INTACT as well as for external young researchers. However, priority will be given to ESR/ER if limitations will be necessary to ensure effective skills training and the development of a team spirit. While the seminars focus on training, the workshops aim at the scientific exchange between the network members and external experts.

In addition to the face-to-face meetings, weekly virtual training seminars will be conducted using modern communication technologies, such as Internet chat-rooms. Mentors from other network teams can also be consulted via chat. The programme of the workshops and seminars will be split: While one part will follow the progress of the studies and address the relevant topic, the other will follow the career development plans of the ESR. During the last year of the ESR in their projects, training in publication and exploitation of the study results will be the focus. In addition, the ESR and ER will be expected to report on the findings of their studies at the workshops in this phase (see table 3).

Summer Schools: Summer schools will offer specific training on the methodology of research on genetic factors and gene-environment interaction for a smaller number of ESR (basic theoretical knowledge will be provided as part of the seminars and workshops and thus be accessible for all ESR). The two specialised centres in London and Utrecht are well known for their summer schools and will adapt their curricula for the purposes of this RTN.

Lecturers: The network assembles a reservoir for lecturers of more than 50 recognised experts. Some examples may illustrate the broad range that is covered by the network partners: As mentioned above, genetics is well covered by the teams from London and Utrecht; training in best clinical practice for the treatment of eating disorders will be guaranteed by the partners in Prague, Geneva and London; the partners in Braga and Budapest will represent the current view of process-outcome research and in addition will focus on the specific public health challenge of underserved groups in rural areas; the partners in St. Etienne together with Hans Hoek (Utrecht) ensure that the transcultural perspective will be well represented; in introducing computer linguistic methods the Heidelberg team in co-operation with the European Med Lab will add an exciting new approach for investigating the influence of media; the industrial partner NetUnion will not only ensure training in

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internet technology on a top level, but also provide the opportunity to learn from a business company how to manage projects and prepare the resulting products for the market.

Experts: Workshops and training seminars will be organised as satellite meetings to the conferences of scientific societies such as the European Council of Eating Disorders and the Eating Disorders Research Society. This will facilitate exchange with external experts. In addition, the RTN will organise two scientific symposia to give the ESR/ER the opportunity to present and discuss their work within the scientific community. Generally, the exchange with external experts is considered as essential for training and knowledge transfer and thus, the INTACT network will always be open for co-operation with external experts.

Table 3: Outline of Workshops, Seminars, and Summer Schools

Training seminars & measures					
Nr.	Time	Measures	Specific topics for: 1 st recruitment wave ⁴	Specific topics for: 2 nd recruitment wave	Organisation
1	month 3	BK	Aetiology incl. genetics, treatment strategies, long-term course		London
		SS	Methodology: assessment measures & technology		
2	month 9	BK	Putative risk factors (cross-sectional perspective)	Aetiology, treatment strategies, long-term course	St. Etienne
		SS	Cultural and sociological perspective on ED	ditto	
		SS		Methodology: assessment & monitoring	
		SS	Reviewing and evaluating research literature	ditto	
3	month 15	SS	Concept: developmental models & process-outcome models of care	Concept: early intervention, flexible treatment strategies, individually tailored intervention, stepped care	Braga
		SS	Public health: under-diagnosed & underserved groups	E-health tools: text messaging, Internet chat-groups	
		CS	Ethics in research	Ethics and law: Specific requirements in e-health	
4	month 18	SS	First summer school on genetics of complex diseases	ditto	London
5	month 21	SS	Advanced methodology & statistics: Stochastic	ditto	Heidelberg
		CS	scientific writing & presentation & publication	ditto	
6	month 27	SS	Concept: longitudinal risk models & process-outcome models of care (integrating results to literature)	Concept: efficacious care for ED – especially, the role of professional and non-professional carers	Prague
		CS	Scientific writing, presentation & publication	ditto	
7	month 30	SS	Second summer school on genetics and biology	ditto	Utrecht
8	month 33	SS	Public health: health economics	Novel methodology: media research, computer linguistics	Heidelberg
		CS	project management, grant writing	ditto	
		TM	Market strategies: deployment of expected products		
9	month 40	SS		Concept: individually tailored stepped care & e-health (integrating results to literature)	Budapest
		CS		Project management, grant writing	
10	month 46	TM		Market strategies for e-health tools for care delivery	Lausanne, Geneva

Note. BK: basic knowledge; SS: special skills; CS: complementary skills; TM: transfer to users & market strategy

⁴ This separation is only for organisational reasons. All ESR take part in the whole programme, but partially in different roles in that those earlier recruited will assist in teaching.

B3 QUALITY/CAPACITY OF THE NETWORK PARTNERSHIP

B3.1 Collective expertise of the network teams

INTACT brings together renowned European experts in genetics, epidemiology, risk modelling, and primary to tertiary treatment with experts on information technology for management, research, treatment, training and dissemination in order to assure that the science is backed up by a strong management and information technology framework. The overall objective of the project is to improve women's health. Thus, we expect that women will be the main beneficiaries. This is the reason, why female scientists and clinicians will have a high profile in the teams at all levels of experience in this project.

INTACT represents a multidisciplinary and inter-sectorial network which bridges a wide variety of disciplines such as clinical psychology, psychiatry, social sciences, and genetics and goes across the age groups from adolescents to adults. This composition reflects the multiplicity of factors determining these disorders. In addition, there is technological competence present which is central to meeting the challenges set by the project with regard to assessment and information flow and the computer mediated delivery of care. Overall, the network has a European dimension, and could not be realized on a national basis. It maximizes the synergy between the contributions of its partners and thus reduces fragmentation in European research and training in the field of eating disorders.

The core members of the network have worked together in the *COST Action B6* from 1994-2001, the *Framework V project "Factors in Healthy Eating"*, and/or the *Framework VI project "SALUT"*. Through these collaborative activities we have learnt to value co-operation on European level. The positive feedback especially from young researchers in our teams has motivated us to initiate this new European collaboration.

The network fosters exchange between researchers from established countries (D, F, NL, UK), new member states (CZ, HUN) and less-favoured regions (North-Portugal) and across sectors. The SME NetUnion will provide specific opportunities for ESR and ER to acquire skills, knowledge and experience that will be vital to their future success as scientists, entrepreneurs or managers. Several undergraduate and graduate students contribute to the research at the network nodes and will benefit from the training opportunities. Thus, the network will include more than 150 researchers of various degrees of experience and expertise. It has the critical mass to foster the growth of a new generation of researchers in the field defined by the project objectives. Its composition ensures synergetic gain and will promote European added value. The network consists of 9 network nodes. Their scientific responsibilities within INTACT are listed in table 4 (see pp.18-19, and table 3, p.22 for the responsibilities of the network partners for training).

Table 4. Responsibilities of the network partners

	Workpackages						across Workpackages		
	WP1: Risk models	WP2: Step-up care	WP3: Process-outcome		WP4: Step-down care		GEN	LING	TECH
			AN	BN	AN	BN			
1 Heidelberg								Res [4]	Res
2 St. Etienne	Res [1]	Part [5]						Part	
3 Prague			Part [9]		Res [13]				
4 London			Part [10]		Part [14]		Res [3]		
5 Budapest				Part [7]		Res [12]			
6 Braga	Part [2]	Res [6]						Part	
7 Utrecht			Res [11]				Res		
8 Geneva				Res [8]					
9 NetUnion									Res

Note. Res = Responsibility; Part = Participating node; GEN = Genetic research and training; LING = Linguistic research; TECH = Technological development and support; AN = Anorexia nervosa; BN = Bulimia nervosa. Indicated in brackets are the reference numbers of the 14 studies (see also table 5, p.37)

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ENDPAGE

MARIE CURIE ACTIONS
Research Training Networks (RTNs)

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Individually Tailored Stepped Care for Women with Eating Disorders