**CREDITS4HEALTH**

Credits-based, people-centric approach for the adoption of healthy life-styles and balanced Mediterranean diet in the frame of social participation and innovation for health promotion.

**Grant agreement n.: 602386**

# Publishable Summary

# 1. Publishable summary

## 1.1 The problem to be addressed

Many researches confirm the looming pandemic of Non Communicable and Chronic Diseases (NCD, CD), which represent the top cause of death worldwide (around 86% of total mortality in Europe), and which killed more than 36 million people in 2008. The majority of these deaths can be attributed to cardiovascular diseases and diabetes, cancers and chronic respiratory diseases. More than 9 millions of these deaths occurred before the age of 60 and could have been largely prevented, tackling risk factors like physical inactivity, raised blood pressure, overweight and obesity, raised cholesterol, tobacco smoking, and raised blood glucose.

The most recent surveys show that the health behaviours driving these chronic diseases are dramatically increasing all over the world as well as in Europe. Around 59% of EU citizens never or seldom take part in physical activity, with a proportion of 42% that never exercises or plays sport (*Sport and Physical Activity*, survey conducted by Eurobarometer, March 2014). Meanwhile, sedentary behaviour is dramatically increasing and, as a result, more than half of the EU population is currently overweight or even obese. The National Healthcare Systems are struggling to propose integrated policies to deliver a comprehensive range of essential primary care services, to ensure early detection and timely treatment of chronic and acute pathologies. However, little is being done in terms of preventative care, and a large proportion of people with high NCD risk remain undiagnosed and untreated.

## 1.2 The C4H Project in a nutshell

Credits4health (C4H) is a social innovation and health promotion project aimed at designing, developing, and testing a preventive healthcare system with the following objectives:

- Reduce sedentary behaviours;
- Enhance the level of physical activity;
- Foster the adoption of healthy dietary styles, with particular focus on the Mediterranean diet.

**Figure 1. The C4H Consortium**

The C4H approach was designed upon evidence-based personalized interventions based on users' existing behaviours and their medical, psychological, and social background; these interventions were delivered through an ICT platform, aimed at stimulating people to become more physically active and to follow a Mediterranean diet by means of personalized paths. The ICT platform allows screening the users in order to identify their specific features related to

dietary and physical habits, as well as their motivations and possible barriers. Users can set their own nutritional and physical activity goals, and are provided with evidence-based tools, suggestions and social support for reaching them: the treatments delivered through the platform aim at enhancing their knowledge and motivation, helping them plan, report, and monitor their activities, and clearing the social and psychological barriers that prevent them from adopting a healthier lifestyle. A substantial innovation of the C4H approach is the introduction of a rewarding system based on the performance of users: depending on the level of compliance with their self-set goals, they earn credits enabling them to access discounts on a set of health-promoting products and services provided by Industrial partners of the project.
The C4H multi-stakeholder approach has been tested in the course of three Pilot Studies, in order to validate its sustainability for all the stakeholders involved, and its scalability with a view of the future industrialization of the system.

### 1.3 The Project Concept

The C4H approach relies on one fundamental concept, which has to be implemented in order to foster the transition to a new approach towards health and well-being: **people empowerment**. This represents a radical shift in societal mind-set, advocated practically by all European governments and National Healthcare Systems: the shift from a one-way delivered healthcare to a multi-stakeholder approach, in which people play the pivotal role, being actively involved in maintaining and improving their health status, being responsible for their well-being, and committing themselves knowingly to an active lifestyle and a healthy diet. C4H is all about supporting people being the authors of their own health and well-being, by providing them with the right stimuli, the knowledge and the tools they need for reaching their personal goals.
The delivery of **personalized paths** tailored to the participants' profile is one of the C4H project's major features. The interactions that participants engage in on the ICT platform deals with three major domains: psychology, nutrition, and physical activity.
Both the baseline assessment of the participants and the subsequent personalized activities pertaining to these domains are based on validated tools and acknowledged methodologies, and have been purposely designed by the Consortium experts.

a. **Motivation**: users are screened through a psychological baseline assessment to define their motivational status regarding changing their dietary and physical activity habits. The participants are then subdivided into clusters, and are asked to undergo a psychological intervention whose main aim is to motivate them to improve their behaviours related to both nutrition and physical activity. This treatment uses important mediators of behaviour change, which are risk perception, outcome expectancies, perceived self-efficacy, planning, and action control/self-monitoring.
b. **Nutrition**: on the basis of anthropometric measures and the C4H nutritional questionnaire (assessing 21 nutritional performance indicators), the platform automatically identifies inadequate dietary behaviours with potential positive changes for the participant (e.g. increase fruit consumption, increase legume consumption, and so on) within the context of the Mediterranean Diet. Users are proposed possible goals based on their status, and can choose the ones that are most suitable to their needs. After goal setting, they can plan their food consumption by means of a weekly calendar, self-report their actual consumption with an easy-to-use interface, and finally monitor their performance. Subsequent evidence-based

nutrition intervention paths are applied, including, among others, educational content, suggestions for recipes and meal planning. Furthermore, a short screener to identify and assess the determinants of the dietary behaviour chosen is administered every two weeks. After having attained their self-set goals, the users can choose other dietary goals, and go on pursuing other health-promoting behaviours. Meanwhile, they can always keep track of the performance related to their past goals by means of specific short questionnaires.

c. **Physical activity**: on the basis of anthropometric measures and the baseline assessment questionnaire – assessing the baseline Physical Activity (PA) performance – participants are segmented into four categories (Inactive, Moderately inactive, Moderately active, and Active), each requiring a certain amount of additional caloric expenditure. Participants can then set their goal, by choosing between various weekly amounts of calories to be burnt (tailored on the basis of their specific physical status), and also between different paths to reach the weekly goal (easy, medium or difficult paths). Based on the set goal and path, the user can choose the activity, the duration, and the intensity in order to meet the planned caloric expenditure, and plan a weekly calendar accordingly. The users can then self-report the performed activities, receiving positive feedback if they are in line with the plan, or being asked to report (through questionnaires) the reasons for not achieving their goal(s). In this, participants get suggestions and strategies to overcome the problems, and the choice to reschedule the activities. The general aim is to help users in setting their PA goals, assessing whether they manage to plan and perform them, and supporting them towards more challenging goals in case of success or helping them understand and tackle the reasons for not reaching their goal(s).

The C4H approach is complemented by the introduction of material incentives as a reward for the effort and the performance reached by the users. Indeed, the use of material or financial incentives has been increasingly adopted by public bodies to stimulate the adoption of behaviours deemed beneficial to both the individuals and the society in which they live. We all know that the gains produced by healthy behaviour and the reduced risk of diseases are perceived as intangible or delayed in time, while financial rewards feel more concrete and immediate, making the adoption of healthy behaviours more attractive. That is why the use of incentives in the health domain is a common practice adopted by governments to change individual behaviours. C4H's approach is based on the use of "positive incentives", since they are used to promote the adoption of healthy behaviours by giving additional resources to the users, and making healthy goods economically more attractive. These positive incentives represent an extrinsic motivation, which is aimed at boosting intrinsic motivation towards a healthier lifestyle. The aim of C4H is thus to contribute with scientific results on the discussion on the effectiveness of incentives in promoting healthy behaviours, and more importantly, to test and possibly identify a sustainable and effective system contributing to the European efforts for preventive care and health promotion.

### 1.4 The C4H intervention on the user perspective

The C4H platform is addressed at people in apparently good health, willing to improve their lifestyles, and provides them with the following services and tools:

- **A baseline screening** aimed at identifying the users' personal profiles, by means of evidence-based assessment tools for defining the anthropometric, socio-psychological, nutritional, and physical activity status of each user.
- **A goal-setting system** tailored to participants on the basis of the baseline screening. Users can choose and customize their own, personalised dietary and physical activity goals, and some of them are recommended based on the screening results. After setting their own goals, users are provided with evidence-based tools, suggestions and social support to reach them.
- **The personalized paths**, which are intended to support the users in reaching their goals. The paths, which are tailored on the specific personal profile and needs of the users, include a series of interactive activities with the purpose of:
    - Enhancing their motivation towards a healthier lifestyle by means of evidence-based psychological interventions, enabling them to combat the personal barriers that prevent them from reaching their nutritional and physical activity goals (for instance, planning, self-reporting, monitoring, feedback on results, and motivational input);
    - Providing them with evidence-based tools, information, and suggestions to enhance their knowledge and reach their objectives, by supporting them in planning and monitoring their dietary and physical activities.
- **Tools providing social and peer support**, that is a social environment that allows users to communicate with other participants, share ideas, organize group activities, and comment on whatever feature of the platform.
- **The rewards system**, which allows users to gain reputational points on the basis of their performance, and eventually use them to get discounts on health- and leisure-related goods and services delivered by C4H industrial partners.

## 1.5 The pilot studies

C4H has conducted three pilot studies in order to put to the test, evaluate and improve both the C4H system (procedures, operations, tools, and assets) and the ICT platform (functionalities, look and feel, usability, stability, etc.)

The first two studies have been on-field tests, mainly aimed at evaluating the platform, its functionalities and users' feedback on the C4H system.

Through a user centred design and participative design approaches, the C4H platform and system have been iteratively refined and expanded with new functionalities and processes, in order to set up and run the final study assessment of the C4H system in the form of a Randomized Controlled Trial (RCT). The three pilot studies have been conducted in four study areas in three European Countries:

1. City of **Florence** (Italy) – *population: around 300,000; territory: around 40 square miles*
2. Region of **Salento** (Italy) – *population: around 1,500,000; territory: around 2,057 square miles*
3. City of **Girona** (Spain) – *population: around 97,000; territory: around 15 square miles*
4. **Pylos Nestor/Kalamata** region (Greece) – *population: around 70,000; territory: around 700 square miles*

**Figure 2. The four pilot study areas**

The first two pilot studies were conducted in 2015, while the RCT study was conducted in the period between December 2015 and July 2016. The following Table provides the main features of the three studies:

| | Pilot 1 | Pilot 2 | Pilot 3 |
|---|---|---|---|
| **High-level objective** | Assess the platform usability and actual usage to refine the platform in Pilot 2. | Assess the platform usability and actual usage to refine the platform in Pilot 3.<br>Introduce and assess the credits system to refine it for Pilot 3. | A Randomized Controlled Trial to:<br>• Assess the effectiveness of the personalized paths in enhancing users' physical activity and nutritional habits.<br>• Assess the effectiveness of the credits system. |
| **Participants** | 450 (150 in Italy, 150 in Spain, 150 in Greece) | 450 (150 in Italy, 150 in Spain, 150 in Greece) | 2100 (700 in Italy, 700 in Spain, 700 in Greece) |
| **Duration** | 2 months | 2-4 months | 6 months |
| **Study procedures** | • Recruitment<br>• Baseline assessment<br>• Platform activities<br>• Final assessment | • Recruitment<br>• Baseline assessment<br>• Platform activities & preliminary credits system<br>• Final assessment | • Recruitment<br>• Baseline assessment (including blood tests)<br>• Platform activities & credits system<br>• Final assessment |

**Table 1. Main features of the 3 Pilot Studies**

### 1.6 Main results of the Project

In the course of the project, the C4H Consortium reached a series of scientific and technological results that can be attributed to the following main categories:

1. Ethics results.
2. Technological results.
3. Communication results.
4. Scientific results.

#### 1.6.1 Ethics results

The Consortium designed and drafted the C4H ethical protocol for both the developmental pilot studies and the final RCT, and submitted them to the Ethics Committees in the four local areas. The C4H trial protocol had to comply with the ethical provisions and legislations at both the European and national levels. The main challenges that the Consortium had to face were twofold. First, the need to fulfil the ethics requirements of 4 areas in 3 different European Countries (given that each Country has specific provisions). Second and most importantly, the introduction of material incentives in an RCT, which represented an absolute novelty for intervention trials in Italy, because of the lack of Italian regulations regarding incentives.

One of the first results of the C4H project is the approval obtained by the Ethics Committees in the four study areas. In Greece, the protocol was submitted to the National Ethics Committee (E.E.D.) for Clinical Studies of the Ministry of Health, which stated that the approval of the National Ethics Committee for Clinical Studies was not needed, since the study had to be considered an "educational" intervention through an electronic platform. Furthermore, it did not imply the administration of drugs nor to any therapeutic intervention.

In Spain, the protocol was submitted to the Bioethical Commission of the University of Barcelona, and obtained the Ethics Approval as an intervention study. The Commission required a certification of insurance due to the presence of blood samples expected for Pilot 3.

In Italy, three protocols have been submitted (one for each pilot) and approved by the local Ethics Committee. C4H was considered a population study/trial, implying that a randomisation procedure towards an individual treatment/non-treatment is possible. Given its nature as a non-pharmacological/non-clinical study (since neither drugs nor therapies were going to be tested), also the use of material incentives was allowed, with an insurance payment required since this Pilot was considered an intervention study. This was indeed an important achievement in Italy, since it is the first trial of this kind officially approved by the Ethics Committee. This can be exploited for similar interventions in the future, which are expected to mainly assess primary intervention strategies.

#### 1.6.2 Technological results

The main technological results pertain to the design and development of the C4H system, and in particular of the ICT platform. The latter obviously contains several foregrounds produced in the course of the project by the scientific group – both new tools for the evaluation of the users, and the algorithms designed for structuring the interventions directed at the users.

The platform is the result of iterative cycles of design, feedback from users, and re-design, as well as a participatory design process. The frontend (user interface) of the ICT platform is centered on a homepage linked with several functional modules (also see Figure 3):

- **Homepage**: highlights on the other sections and easy-to-understand indicators for a brief overview of the current user's performances;
- **Diaries**: goal progress and goal settings, diary management;
- **Steps**: monitor of daily steps through the use of a PA tracker (pedometer);
- **Social**: forum for the C4H community interaction, based on various channels/topics;
- **WIKIs**: suggestions, guidelines, and content on nutrition and physical activity;
- **Rewards**: credits management, products/services offers, credits redemption.

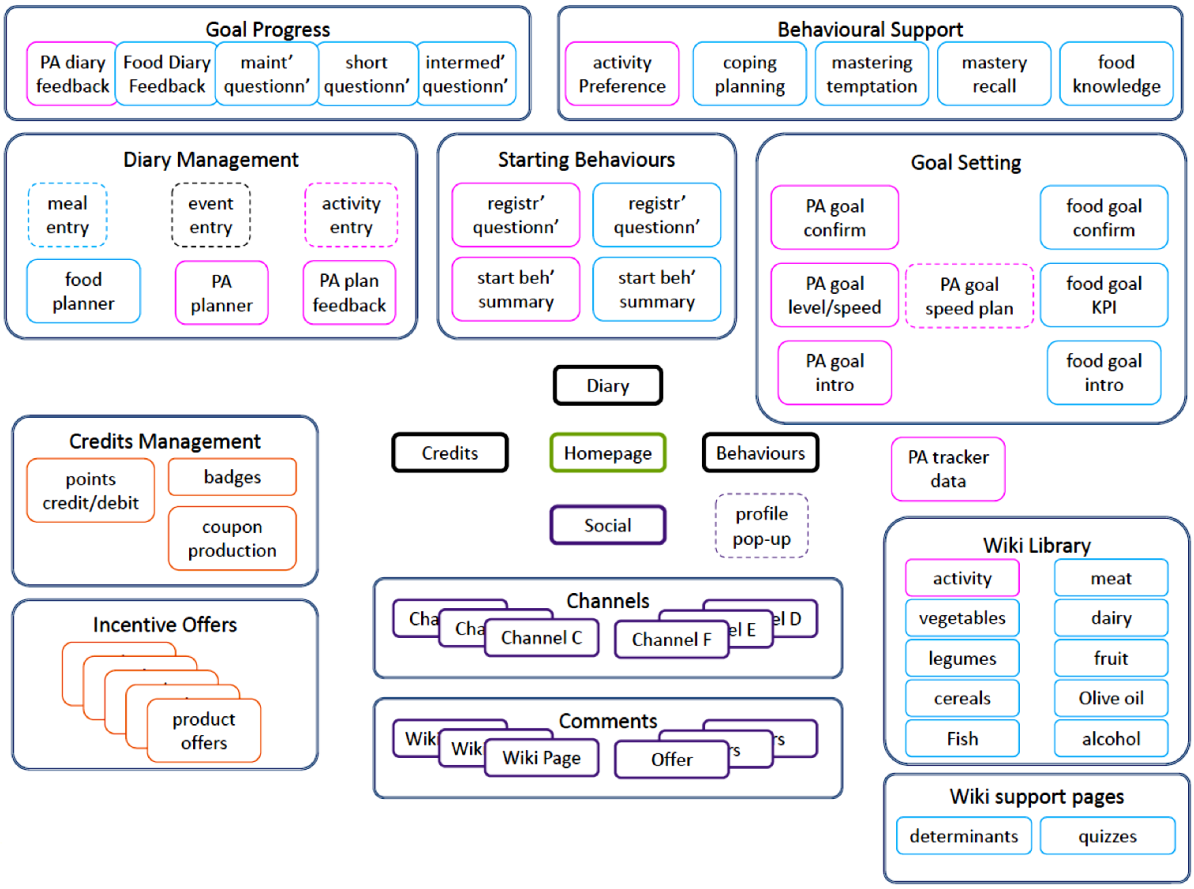



**Figure 3. Organisation of the C4H platform's frontend**

After having filled in the on-line screening questionnaires, the user enters the homepage of the platform. Here, s/he can find the most important information provided by the platform and based on user's performance: number of points gained in each of the rewarded categories of actions (users can gain points out of 5 different categories); the main diagrams related to PA tracker (evolution of the steps during last week or month, etc.); the week performances against the weekly goals (Kcal burnt for each day against the Kcal planned; self-reported food consumption against the planned consumption in relation to the dietary goals chosen); highlights on the last social threads and messages; then access to content pages, quizzes, and interactive section, as well as the credits section. Through the homepage section, the user can also access the personal info page (for changing settings, uploading photo for the user profile, etc.), and the help page (for getting guidelines about the platform and support by the C4H assistance).

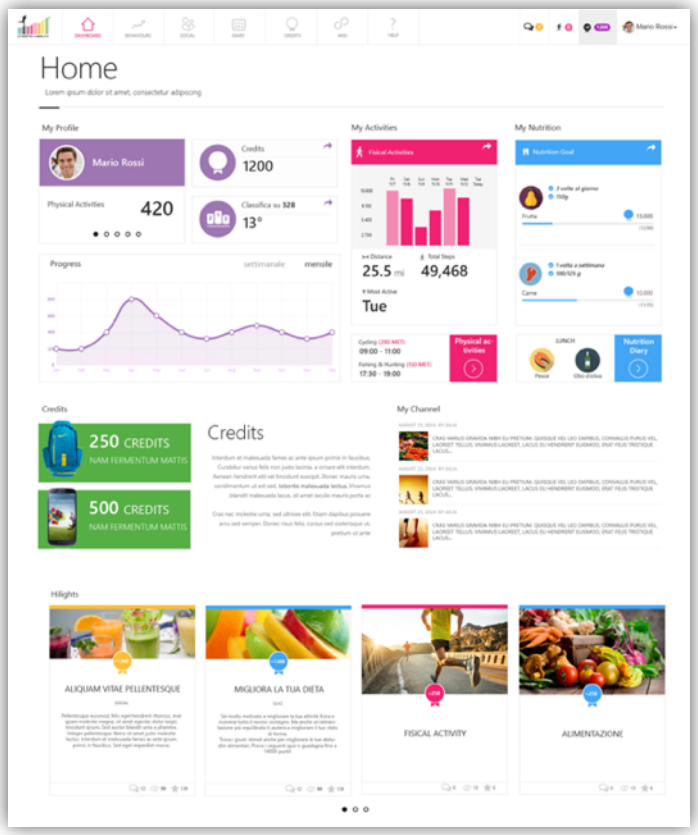



**Figure 4. The Homepage**

The other fundamental element of the Platform are the diaries. First, users have to set their goals with regard to both nutrition and diet. Goal setting is as easy as going through 3 steps: for nutrition, users choose two dietary habits they want to improve (for instance, increase consumption of fruit and vegetable) out of those recommended by the platform; for physical activity, they choose the weekly target caloric consumption and the path (or speed) to reach the target consumption. Goals can be changed at any time, especially in case the user finds out that the goals set are too demanding or too easy to reach.

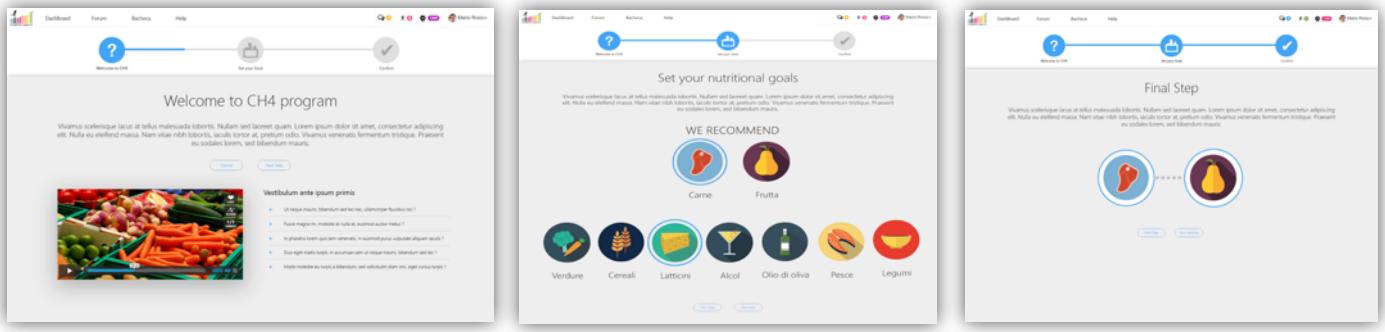



**Figure 5. Nutrition Goal setting in 3 steps**

After goal setting, the users can plan their activities by using two calendars (one for physical activity, the other for nutrition). With a simple drag and drop system, they select an activity by just placing it within the planned date and hour of the day, and edit properties of the activity.

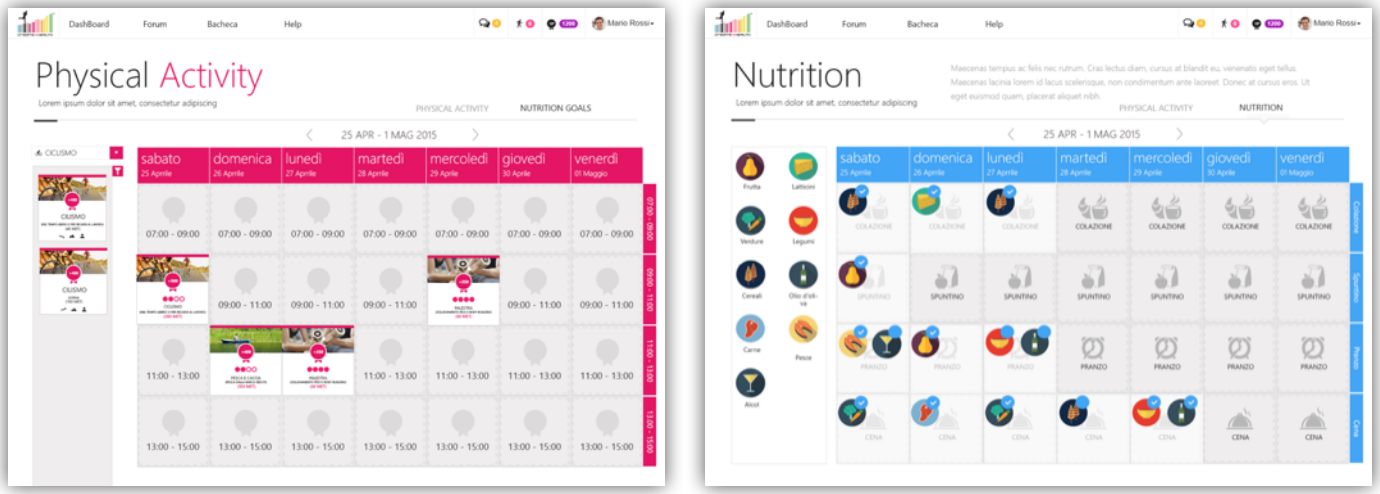



**Figure 6. The PA and nutrition calendars**

The page dedicated to PA Tracker is full of information about the steps performed in the current day, and statistics with regard to the previous days (evolution over the week and the month). It is complemented by several comparison data, on both personal and others' benchmarks. Indeed, users can compare data with their own daily average, or even day of the week's average. They can also compare their data with the average of the community, or the average of the users with similar characteristics (same gender, same age-range, same study area, and so on).

**Figure 7. Examples of data provided by the C4H Step page**

The social features of the platform are very important, too. On one hand, the platform presents a section entirely dedicated to social support, with a forum where users can interact, discuss, and organize group events. This section is subdivided into topics, so that users can participate just in those discussions they are interested in. Users can also select some favourite discussions, and they are informed in the homepage about new posts in those particular threads. On the other hand, it has to be highlighted that the platform has also social features embedded in its overall structure. Users can add comments and start threads also in the content pages of the platform (for instance, at the end of the WIKI nutrition or PA content), as well as share at any time in the social forum their performance, successes, or information about their status.

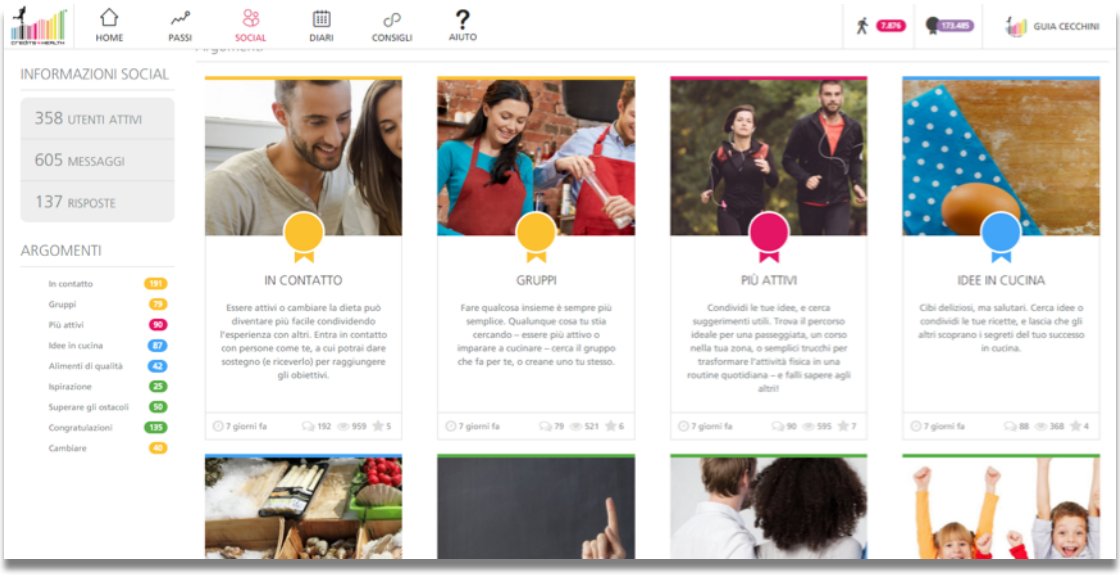



**Figure 8. The social page, redirecting to the various threads**

In the platform, users can also find lots of educational content, suggestions, interactive activities to learn about the benefits of the Mediterranean diet, the properties of food categories, and many other topics. The WIKI pages are dedicated to nutrition and physical activity. They provide immediately applicable suggestions and guidelines for a proper food consumption and good exercise habits, and allow the users to go deeper into a topic and learn a lot more.

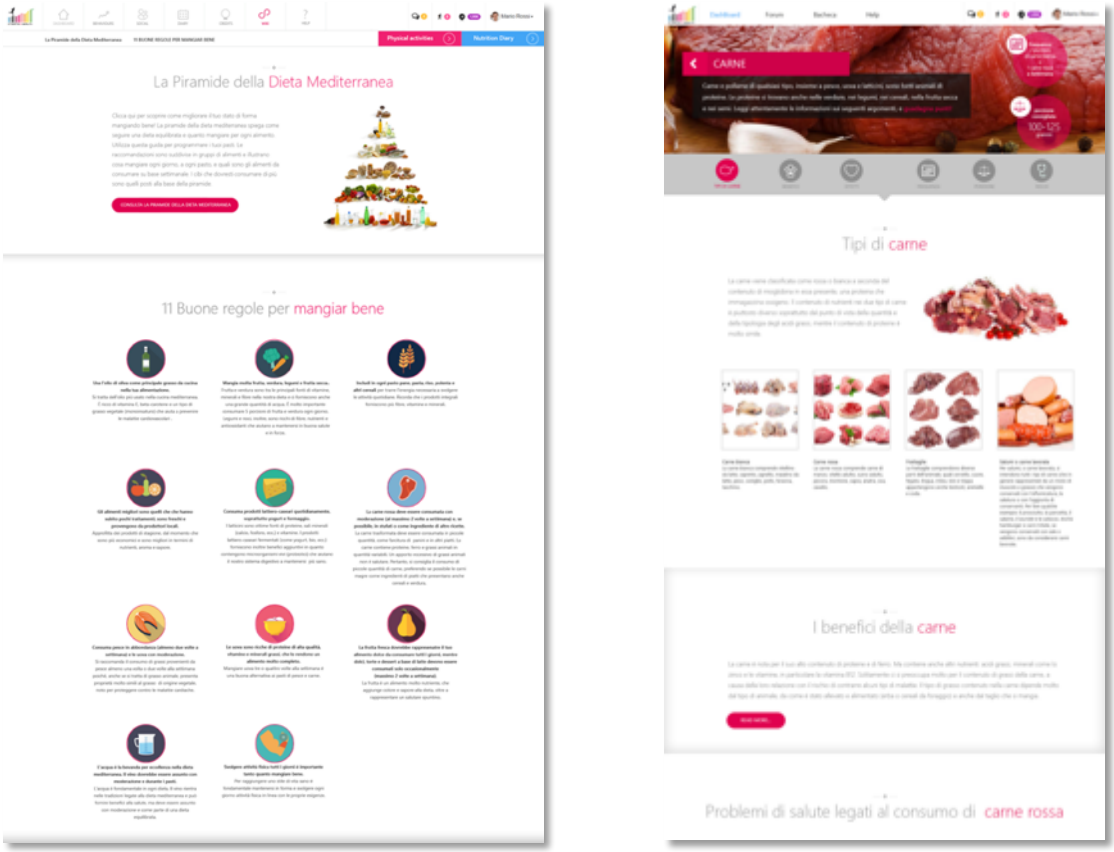



**Figure 9. Two examples of WIKI content on nutrition**

The credits module provides users with the possibility to redeem their credits for rewards. This module features:

- a main credits system page, where the user can browse into the various products and services offered by the C4H industrial partners;
- the offer page, which shows in detail each offer, the main info (pictures, requirements, cost in credits, value in Euros, etc.) and allows users to convert their credits into a discount coupon;
- The confirmation page, which pops up at the end of the voucher-emission process;
- The vouchers history, which gives users the possibility to see all the subscribed offers and obtain a copy of the coupon.

With the coupon, the user can go directly to physical or on-line shops of the C4H Industrial Partner and buy the product/service with the agreed discount.

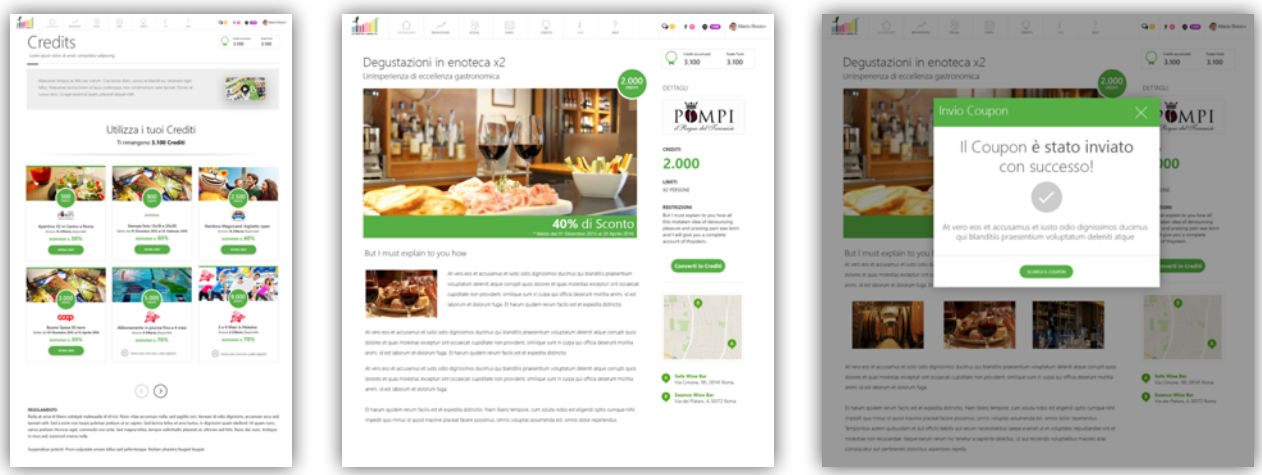
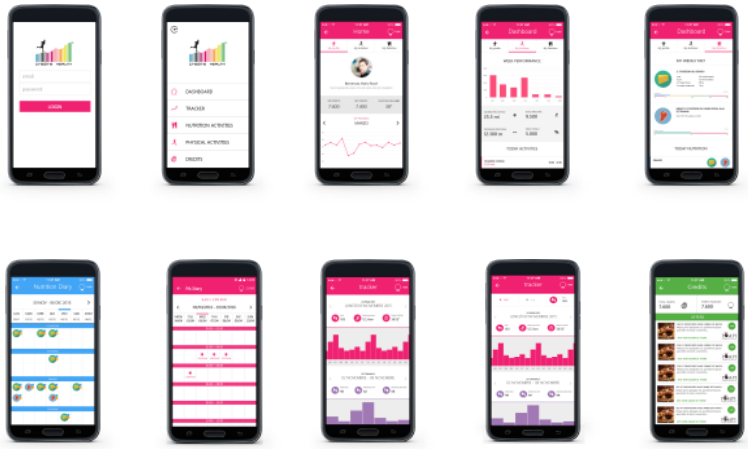



**Figure 10. Three pages from the Rewards section**

Besides the C4H platform, the C4H mobile application has been created for giving users an optimized experience, allowing them to use C4H wherever they go. The key points of the implementation are:



- Development for one technological platform (Android), favouring the one with the highest market-share;
- Implementation of the primary features for the system;
- Integration with the server system, using the services already implemented;
- User experience consistent with the one of the web version.

**Figure 11. Screenshoots of the C4H mobile app**

Other interesting features of the platform are:

- The guidelines on how to use the platform and the integrated Tracker device, with lots of video and text content for guiding the user in navigating and actually using the platform.
- The incident management system, which is embedded in the platform and allows users to contact directly the assistance by sending a form (with the explanation of the problem they encountered or the suggestion they need). The system also allows users and assistance to interact in real time, like in a chat, to facilitate direct contact. Furthermore, the incident management allows for collecting all the incidents, categorize them, and prioritize them, and to intervene technically on those that have more occurrences or impact on the system.
- A rewarding system embedded in the platform that provides credits on a daily basis, to reinforce the commitment of the user in the activities. Performances are rewarded with more credits, but also other actions in the platform (like writing posts or answering questionnaires) are rewarded, to motivate the users in undergoing the full intervention.

### 1.6.3 Communication results

Usually, communication results are related to the dissemination of the project results or the scientific dissemination. In the case of C4H, communication has been a core activity, because during the project, more than 2,500 people from three different Countries were enrolled in the pilot studies. One peculiarity of C4H when compared to other research projects is the relationship with people created during the project duration: almost 600 people have been the alpha and beta testers of the C4H platform, using the functionalities, highlighting problems and strengths, and providing feedback. Additionally, more than 2,000 people were enrolled in the final RCT study and contributed to the collection of a huge amount of data. This will enable the C4H Consortium's scientific group to find correlations amongst the users' social, psychological and physical status.

**Figure 12. Press conference for the launch of the project –The Italian Minister of Health Beatrice Lorenzin (left), and the C4H Coordinator Maria Luisa Brandi (right)**

The first official communication of the C4H project has been the Launch Press Conference in Rome (Italy), at the presence of the Italian Health Minister. Then, the project has been advertised for enrolling the users by means of various on-line and off-line channels – the website, the FB page, Google AdWords campaigns, as well as advertising on press, newspapers, radio and so on.

Over a period of around one year, in which the enrolment to the study has been active, the communication partner collected more than 750 press clippings about C4H from newspaper, web-channels, radio broadcasts, and so on in the local areas of the study.

Another fundamental result has been the organization in the areas of the study of events dedicated to physical activity and nutrition and sponsored by C4H. Two of them proven very successful, in

Florence and in Girona, with thousands of people involved in activities related to wellbeing, nutrition, sport and also the involvement of C4H Industrial partners and other local producers. The videos of the two events can be found here:

C4H event in Florence: https://youtu.be/Wkwy46IwE4Y

C4H event in Girona: https://youtu.be/OpA99at3meM

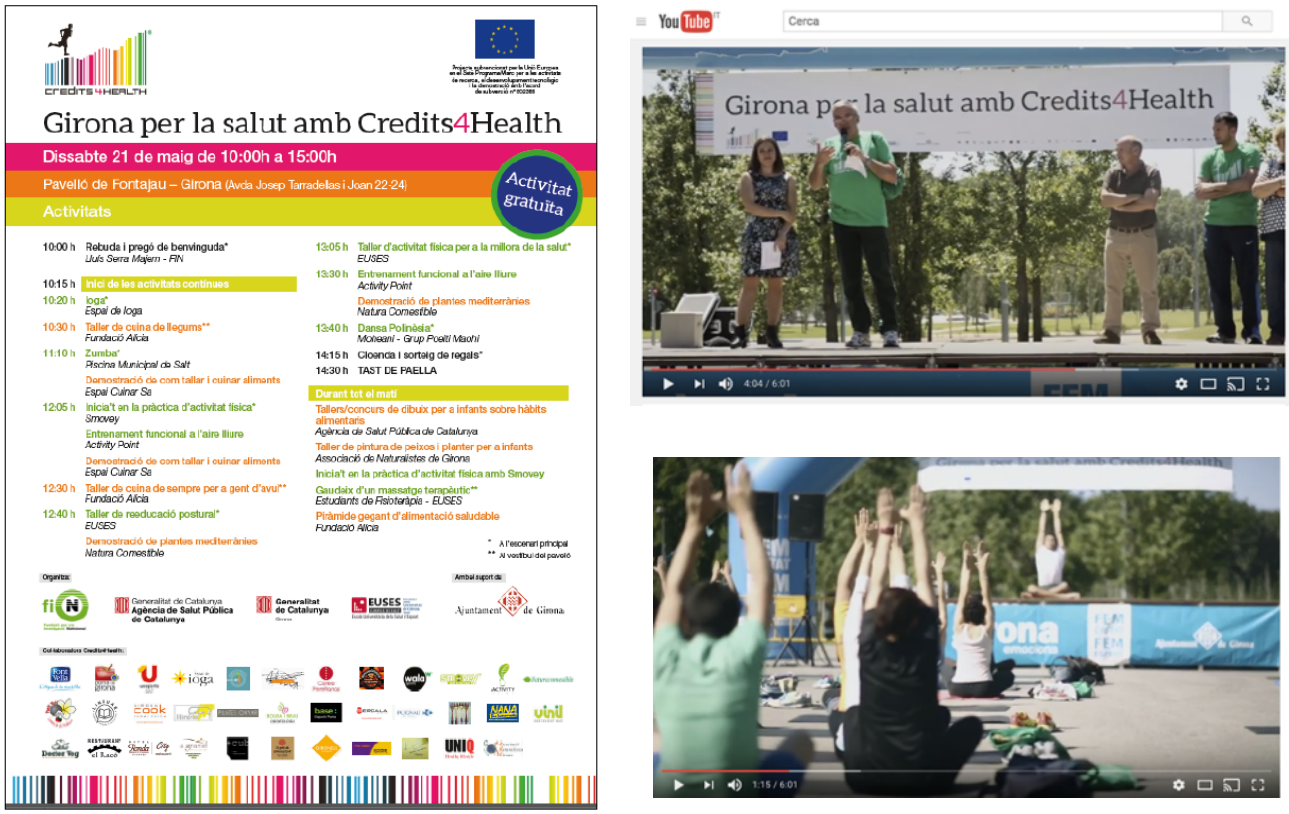



**Figure 13. C4H in Girona, program and images taken from the video**

**Figure 14. C4H event in Florence: Gadgets, medical monitoring and physical activity in the city center (images taken from the video)**

### 1.6.4 Scientific results

Scientific results can be subdivided in two different types:

1. Scientific foreground generated during the project.
2. Data collected during the project, which are being analysed, and contributed and will contribute to producing scientific papers.

The scientific foreground generated during the project is related to several tools and algorithms designed for screening users, their nutrition habits, their psychological/motivational status, and so on. In particular, they can be summarized as follows:

- **The medical segmentation of users**: an evidence-based medical model for screening users on the basis of their medical conditions has been developed. This served to define eligibility criteria to participate in the pilot studies, but also to cluster participants and provide personalized recommendation based on their medical status.
- **The psychological segmentation of users**: A survey on the three pilot countries was conducted using a 60-item multi-lingual psychometric tool, where psychosocial variables were selected to assess participants' readiness to change for nutrition and physical activity. Data collected and analysed brought to the development of a psychological assessment tool regarding nutrition and physical activity, to be used as baseline and follow-up assessments (in 4 languages).
- **The algorithms** for delivering the interventions on the platform. The physical activity and nutrition interventions were developed starting from evidence-based tools and focusing on specific features:
    - a baseline screening to assess the user status;
    - a goal-setting system which suggests personalized goals to the user;
    - a set of tools for supporting the users in reaching their goals (self-planning and monitoring tools);
    - a feedback system able to support the users during their performance;
    - social interaction and social support tools.
- **The C4H nutritional questionnaire**: A pre-post, semi-quantitative nutrition questionnaire consisting of 35 questions that assess 21 nutrition-related habits through quantitative indicators at baseline evaluation and at the end of the study, thus providing quantitative data on participants' performance. The purpose is to identify inadequate diet-related behaviours, which might cause health problems and which participants are recommended to address in goal setting including the nutrition intervention pathways provided by the C4H platform.
- **C4H Mediterranean Diet Adherence score**. A C4H score to evaluate the adherence to the Mediterranean Diet, which constitutes one of the primary outcomes for nutrition in the RCT phase of the project. The aim was to incorporate an indicator that would reflect the diet pattern as a whole and not just specific food groups comprising the Mediterranean diet. To create the score, an evaluation external to the C4H project was conducted, administering a reduced version of the C4H Nutrition Baseline questionnaire and comparing two different scoring systems (simple and complex) in a sample of two hundred individuals. For the C4H questionnaire, the two scores were in good agreement. Nevertheless, further research is

needed to define/quantify lifestyle characteristics that capture the sustainability and conviviality of this diet.

With particular reference to the structure of the various Work Packages included in the project, the results can be described as follows:

| **Work Package 1: PROJECT FOUNDATIONS** |
|---|
| ✓ Analysis of potential stakeholders, both positive and negative, which are expected to affect the C4H ecosystem, and definition of the best strategies to involve and manage the selected stakeholders of the project (for instance, the Industrial Partners).<br>✓ Strategic inputs to involve and manage the stakeholders' commitment, mainly based on surveys conducted on a group of selected stakeholders.<br>✓ Analysis of the possible scenarios in which the C4H system has been tested, in order to better define the opportunities and the constraints of the active participation in the project by all the stakeholder involved. The analysis of the local C4H sites has been conducted by using a large number of both quantitative and qualitative data investigated through a specific survey. Each scenario is described in terms of the people's perception of the social environment, the impact of their perception on health behaviour, and socio-ecological characteristics of the sites. The scenario studies also produced a scientific paper currently under review by the *Social Indicators Research* journal.<br>✓ Definition of user requirements through a participatory design process, which involved experts in behaviour science, digital tools, and end-users for testing the platform and providing their feedback. Elaboration of the feedback in order to define new requirements for the system and the ICT platform.<br>✓ Definition of the operating principles of the whole C4H initiative, based also on the results of the stakeholder and scenario analysis and the feedback from potential stakeholders and end-users. This allowed defining the stakeholders to be involved and how to involve them, how to structure the C4H system with a view of its possible industrialization, how to use credits, the fundamental procedures and workflows for running and monitoring the C4H initiative. It also included the definition of the user requirements by taking into account all the regulatory, business and technological provisions for developing the C4H initiative.<br>✓ Development a model for assessing both the economic and the societal impact of the C4H project, in order to verify the long-term economic sustainability of the initiative with a view of its possible rollout in other European Countries. |

| **Work Package 2: USERS SEGMENTATION** |
|---|
| ✓ Develop the Medical Segmentation Model, enabling a medical clustering of participants on the basis of their clinical condition. This included the definition of evidenced-based eligibility criteria for participation in the C4H program, as well as of system for the clinical evaluation of the enrolled subjects in line with the project needs. |

- ✓ Definition of a model for the segmentation of the subjects from a theoretical and empirical point of view, in order to tailor intervention procedures through the platform.
- ✓ Elaboration of evidence-based general recommendations to be delivered on the basis of the clinical status of the subjects.
- ✓ Design of a 60-item multi-lingual psychometric tool ("pre-test"), where psychosocial variables were selected to assess participants' readiness to change their dietary and physical activity habits. This led to the implementation of an online survey and collection of data in three countries. A paper has been published in *The British Journal of Health Psychology* on this 60-item psychometric tool.
- ✓ Development of a 21-item psychological assessment tool in 4 languages (Spanish, Catalan, Italian, and Greek) regarding nutrition and physical activity, to be used as baseline and follow-up assessments in the project.
- ✓ Development of a segmentation model for Pilot 1 based on the online survey data. This segmentation procedure is a cluster-based and regression-based staging algorithm assigning participants to psychological profile groups.
- ✓ The analysis of the data collected through the 21-item psychological assessment tool led to a scientific paper published by the *Public Health Nutrition* journal.

**Work Package 3: PERSONALIZED PATHS**

- ✓ Design and development of the physical activity algorithm, with a screening system for clustering users, a goal setting system based on acknowledged recommendations, physical activity self-planning and self-monitoring tools, a feedback system providing input related to the performance and support.
- ✓ Design and development of the nutritional algorithm, based on a screening questionnaire to assess dietary habits, a content-related system for supporting and informing users on good dietary habits, a calendar for planning and self-monitoring, and specific monitoring tools linked to each dietary habit.
- ✓ A social support system based on a social forum in the platform, where users can interact and share their performances and results. Organized in main topics, the forum has been monitored by local moderators (to avoid possible occurrence of stigmatization or unethical behaviours). These social features have been further locally enhanced by the organization of PA and nutrition events by the pilot leaders involving the C4H end-users.
- ✓ Creation of C4H specific nutrition tools, like the C4H nutrition questionnaire for assessing users' dietary habits and the Mediterranean Diet Adherence Score.

**Work Package 4: ICT INFRASTRUCTURE**

- ✓ Design and development of the recruiter application, software used by the recruiters for screening and enrolling participants.

- ✓ Design and Development of the Final version of the Platform with the software modules customized for C4H – database, Back-end interface, and Front-end interface (for users and recruiters) – starting from all the requirements collected and analysed after Pilot 1 and 2.
- ✓ Development of Users Personal Data Protection and backup system.
- ✓ Integration of a specific PA tracker in the C4H system and, through the cooperation with an existing technology platform (Validic) for managing PA tracker data, a possible integration of any other (current or future) brand of PA devices.
- ✓ Development of the DSS (Decision Support System), which implements the algorithms and rules for processing the psychological, nutritional and physical activity data, and which generates output to propose and control interventions in the final platform.
- ✓ Creation of a market-oriented incident management tool for managing the issues (ticket) faced by users when they contact the assistance.
- ✓ Creation of a C4H mobile app running as a complement of the desktop platform intervention.

**Work Package 5: PILOT PROJECTS MANAGEMENT**

- ✓ Definition and draft of the C4H Pilot Studies protocol in compliance with the legislation and ethics provisions for conducting research involving human subjects.
- ✓ Ethical Approval obtained in the four Pilot Areas for running the studies.
- ✓ Definition of procedures, workflows, responsibilities, assets and test standards (with monitoring tools) for running the Pilot Studies.
- ✓ Analysis of the main non-epidemiologic ethics issues in C4H, definition of a system for monitoring them during the Pilot studies, and delivery of monitoring analysis results.
- ✓ Set up all the organization needed to run the Pilot studies, in particular the assistance services to users, and actual local execution of the three studies.
- ✓ Definition of tools and procedures for collecting and analysing data retrieved during the Pilot studies, in order to provide re-design input to the Consortium.
- ✓ Collection of data (usage data, questionnaires, procedural/operations data) and analysis for providing feedback to re-design the system to WPs 1-4 from pilot to pilot.

**Work Package 6: CREDITS4HEALTH ASSESSMENT AND FULL ROLL-OUT**

- ✓ Assessment of the project from a scientific perspective, from an economic and social impact perspective, and from an operational/procedural perspective.
- ✓ Cost-benefit analysis of the C4H initiative, by highlighting the major advantages of adopting the system for the main stakeholders involved: end-users, public institutions at a national level (for instance, the National Health Service) and at a local level (for instance, a municipality or a district), potential private customers (big enterprises interested in wellness programs for their employees).
- ✓ Definition of the industrial plan of the project, with definition of the product/service, the users' needs, the overall market, the added values of C4H, the business model, the main stakeholders

involved, the competitive scenario, the development plan, and the eco-fin projections. The industrial plan also contains an analysis of the conditions for standardizing the approach and making sustainable in the European Countries.

**Work Package 7: COMMUNICATION AND DISSEMINATION**

- ✓ Participation in 15 Scientific Conferences, where the Partners have presented C4H by means of posters, abstracts, and oral presentation.
- ✓ Organization by Partner LMU of the conference "The ethics of health incentive programs" sponsored by C4H.
- ✓ Three published papers, in the *British Journal of Health Psychology*, in the journal *Public Health Nutrition*, and in the *Journal of Medical Ethics*, coming from the activities performed respectively in Task 2.2 (first two publications) and 5.1.
- ✓ A paper submitted and currently under review by the *Social Indicators Research* journal.
- ✓ Collaboration established with UCL's Centre for Behaviour Change (CBC) to develop academic behaviour change networks across Europe, which led to the creation of the CBC Digi-hub in association with Credits4Health, which can count on 400 members all over the world.
- ✓ A massive communication activity both at European and national level (in the four Countries of the Pilot study), which involved a set of on-line and off-line tools and activities. Production of a massive press review of all the articles, radio advertising, videos and other media where the C4H project has been disseminated.
- ✓ Production of an event and publication plan for the after-project activities.

**Work Package 8: IPR PROTECTION AND EXPLOITATION**

- ✓ IPR identification analysis, with definition and identification of the Background Table and of the Foreground Table. Identification of the owners of each foreground. In case of joint ownership, definition of the shares of propriety through joint ownership agreements by the partners involved.
- ✓ Definition of the most suitable means for protecting the Foregrounds.
- ✓ Identification of possible strategies for exploiting the C4H system and platform as a whole. Choice by the Consortium of the most suitable one, based on the constitution of a start-up.
- ✓ Definition of a precise roadmap with a specific set of actions that each partner has to accomplish in order to constitute the start-up company, license the foregrounds to the company (with a royalty reward for the licensing parties), and for defining a sound development plan based on the investment of the required resources by the company shareholders.

### 1.6.5 Scientific analysis

**Preliminary Pilot 1&2 studies**

Platform Pilot 1-2 served to set up the actual ICT platform to be tested in Pilot 3.

People demonstrated their interest to interact with an ICT platform for their health, although the effectiveness of this intervention was not straightforward. People experienced some troubles in the interaction with the platform, as stated elsewhere, but there has been a very committed group that used the platform in Pilot 1 and still wanted to continue into Pilot 2.

This means that this type of ICT intervention did empower the participants and conducted them to follow a healthier lifestyle. This is evident from psychological and physical activity results: the psychological measures show that participants of the longitudinal sample, reported an increase in their motivation to engage in healthy eating and regular exercise (i.e., intention), were more confident to achieve this (i.e., self-efficacy), and had even more positive outcome expectancies as a result of engaging in a healthy lifestyle.

The physical activity level results to be improved from the beginning to the end of the study period both in Pilot 1 participants and in Pilot 2 ones. Although the difficulties encountered in platform usage, it's evident that the C4H platform has been appealing for inactive people that improved both their number of steps and access to the platform itself.

Nutritional behaviour has improved both in Pilot 1 and Pilot 2 even if for different food groups and habits.

The platform improved certain food habits in the participants, as demonstrated by the consumption of fish, fruit and vegetables, legumes, unsalted nuts and seeds, regular olives, and eggs. There was also an increase in some nutritional and lifestyle habits such as the breakfast consumption and also the total number of hours of sleep.

The anthropometric parameters are improved in the first period of the study, during Pilot 1, for the total population and in all age groups, but in the Pilot 2 this trend is not confirmed. In effect, considering that many users of Pilot 1 study continued into Pilot 2, it is likely that, while maintaining high motivation or efficient level of physical activity and nutrition habits, the intervention time was not sufficient to determine evident changes in anthropometric parameters.

**The Randomized Controlled Trial - Scientific Results**

The C4H randomized controlled trial (RCT), formerly referred to as Pilot 3 in the approved protocol for Pilot 1, is designed to prove the efficacy and effectiveness of the previously developed and tested ICT platform together with a credit system in order to improve health-related behaviors through the adoption of healthier lifestyles amongst adult people in apparent good health living in Mediterranean Countries.

The block-randomized design have been developed using an automated algorithm to ensure balanced distribution of participant characteristics across the intervention and control groups: the treatment group received the intervention through the ICT platform plus the credit system ("dynamic platform" with personalized paths), while the control group received no treatment (they could log in a "static platform" which provided general information on good health-related behaviours without no interaction nor personalized paths).

The outreach campaign to recruit Pilot 3 participants was initiated on October 2015. The baseline evaluation was conducted from October 2015 to January 2016. The C4H platform was launched on

December 2015. A total of 2064 individuals attended the initial visit at the centre (361 in Florence, 372 in Salento, 713 in Girona and 618 in Kalamata).

*Psychological results*

For the evaluation of psychological outcomes of Pilot 3, we included the 21-item multi-language psychological questionnaire regarding nutrition and physical activity in four languages (Spanish, Catalan, Italian, and Greek).

At the final assessment point, participants who used the dynamic platform reported to perceive more positive outcomes as a result of eating healthily, were generally more confident in their ability to change their eating behavior, and were more motivated to change their behavior than participants who were allocated to the static platform

At the final assessment point, participants who used the dynamic platform reported to perceive more positive outcomes as a result of exercising and were slightly more motivated to change their physical activity than participants who were allocated to the static platform

Across both intervention groups, men perceived more positive exercise outcomes than women, whereas women appeared to be more confident about increasing their physical activity

A similar trend could be observed for those psychological variables that are relevant for translating physical activity intentions into actual behavior.

The objective of Sociological/Psychological analysis of Pilot 1&2 was to design a *psycho-social* segmentation model of study participants according to their psychological characteristics. We have chosen three different approaches: 1) a multi-method 6-scale rationale resulting in two behavior-specific algorithms (diet, exercise) that provided a dichotomous classification of individuals at baseline into those with rather low motivation/volition and those with rather high motivation/volition; 2) a 10-scales cluster analysis that resulted in three clusters for each behavior (diet, exercise) at baseline; 3) theory-guided stages of change based on a single item for each behavior.

The current preliminary findings shed light on the interrelationships between these *psycho-social* segmentation models over time, also considering allocation to experimental conditions. One of the major findings is that study participants benefit from their platform engagement in terms of their psychological readiness to adopt and maintain health behaviors.

*Physical Activity Results*

The main aim of the analysis of data collected during the RCT study was the comparison of the C4H platform (dynamic platform) with the control platform (static platform). The comparison focused on the amount of physical activity performed by the participants that were assigned randomly to one of the two platforms. The amount of physical activity was assessed in terms of overall number of steps performed over the treatment period, as esteemed by the PA tracker. Moreover, the self-estimation of the physical activity by means of a questionnaire assessing the baseline PA level (namely the GPPAQ) was considered.

Both platforms were able to favour/support an increase of the level of physical activity – as resulted by the comparisons between the pre-post self-assessment carried out by means of the GPPAQ.

The two platforms resulted to have different impact, yet only for women having a middle/moderate level of activity at the beginning of the period of treatment. For this segment of users the dynamic platform showed to be able to incentivise the physical activity (as assessed independently by the number of steps measured by the PA tracker) more than the static platform.

*Nutrition habits results*

The adherence to the Mediterranean Diet (MD) was defined with the simple and complex C4H Mediterranean Diet Score using 35 items representing the food groups and food behaviour most representative of the MD. Every item was given a punctuation of 0 or 1 (in the simple score), and 0, 1 or 2 (in the complex score) in order to elaborate a C4H Mediterranean Diet Score.

The intervention resulted in an increase in the adherence to the C4H recommendations in terms of increasing the food groups that are beneficial for health outcomes and decreasing the consumption of food groups that are less recommended.

Both the dynamic and static platform produced an increase in the number of people adhering to the C4H recommendations, being the improvements higher in the dynamic platform. For instance, in the dynamic platform, there was an increase in the consumption of olive oil, fish, fruit and vegetables, legumes, wholegrain cereals and water; and there was a decrease in the consumption other fats and oils, potatoes, cereals, pizza, sugar sweetened beverages, commercial sweets or pastries, dairy products, red meat, white meat, highly processed products, red wine, high alcohol beverages, fast food and junk food. Participants in the static platform improved their food habits by increasing the intake of fish, and vegetables, and by decreasing the frequency of consumption of potatoes, cereals, and pizza.

The C4H platform improved the adherence to the Mediterranean Diet, with an increase in the complex C4H MD score, especially individuals assigned to the dynamic platform. The intervention delivered through the platform resulted in an increase in the number of participants classified as having a high adherence to the C4H MD score.

*The role of social support in the overall efficacy of the intervention*

Social support measures, aspects of comprehensiveness, evaluation of key constructs of social support, strength of psychometrics, reliability, and validity of each instrument, the Social Support Questionnaire - SSQ by NHANES 2005 was selected for the evaluation of participants entering the C4H platform.

We focused on emotional support, perceived support, tangible support, companionship support and the degree of integration in social networks. This set of parameters is usually used by default in the literature as effect moderators or effect modifiers. Beyond their traditional and operational use, the additional rationale for capturing them in C4H was to optimally create a prognostic model which would ideally predict the intervention-related outcomes and further identify clusters of participants susceptible to certain variations of this complex intervention.

In summary: No association was observed between the social support status and the physical activity status at baseline, even if the presence of a very small percentage of participants with no support or no need for support renders our observations prone to type-II error ("false negative"); participants who reported that could not have used more emotional support that actually received seem to have benefited more from the dynamic platform in terms of their PA status compared to those who stated to be in need for more social support without statistically significant between-group differences; participants who reported that they never attended church seemed to have benefited more from the dynamic platform in terms of their PA status compared to those who stated some church attendance without statistically significant between-group differences; no association was observed between the presence of potential financial support and the physical activity status at baseline.

In conclusion, the main results obtained by means of the intervention through the dynamic platform consist in an improvement in nutritional habits widely shown by an improvement in the adherence to the Mediterranean diet in the subjects who used the dynamic platform than the static.
Participants who received the intervention by the dynamic platform, resulted to be more conscious of being able to get the benefits of a healthier diet and are therefore more motivated to change their eating behavior. The same observation can be done with regard to the study of perception of improvement physical activity, even if in this case the motivation to change the way of life was less effective.
These results are even more important in light of the fact that good nutrition and adequate level of physical activity continue, today, to be undoubtedly associated with a substantial reduction in the risk of occurrence of chronic degenerative diseases and cardiovascular risk.
The achievement of the C4H study indicate that a personalised, automated prevention and intervention programme elaborated by specialists in the field and directed towards people in apparent good health is effective in improving dietary habits, physical activity psychological traits, and social interaction. Therefore, this program can be also proposed in the long term in order to be effective in preventing chronic diseases in a large population not easily reached with proper evidenced-based interventions directly mediated by the medical community.

### 1.7 Dissemination and exploitation of the results

During the execution of the C4H project, the Consortium has been deeply engaged in the organization, set up, and running of the three Pilot Studies. The first two pilot studies have been mainly on-field test of the system and of the platform, mostly aimed at testing the functionalities and stability of the platform and to improve them in view of the most important study, Pilot 3, which was the Randomized Controlled Trial.

Therefore, the major scientific results were expected as a outcome of the scientific trial, which has been conducted in 2016, and ended at the end of July 2016 with the completion of the final screenings of the users. Scientific dissemination had to take into account the fact that the most relevant scientific data would be available at the very end of the project.

For this reason, the scientific dissemination during the project mostly relied on the design of the studies and of the whole C4H system (mainly disseminated through posters and presentations), the design and/or the tools implemented for running the interventions in the study (for instance, the Mediterranean Diet Adherence Score), specific sectors of analysis which were not dependent on the results of the study (e.g. ethical topics), and also the results coming from the analysis of data collected in the pilot studies or even before with possible end-users through specific surveys.

Besides several conferences, national events, and workshops, the most relevant events where oral presentations, as well as poster and abstract presentations took place are as follows:

- 17th European Health Forum (October the 1st-3rd, 2014, Gastein, Austria);
- III World Congress of Public Health Nutrition (November the 9th-12th 2014, Las Palmas de Gran Canaria, Spain);
- 5th International Conference on Digital Health (May the 18th-20th 2015, Florence, Italy);
- Conference Ethics and Food (June the 19th 2015, Milan, Italy);
- Third International Congress on Sports Science Research and Technology Support – European Project Space (November the 15th-17th, 2015, Lisbon, Portugal);
- Public Health Research Workshop –Exploring physical activity for health and fun (March the 10th 2016, Glasgow, National Football Stadium of Scotland Hampden Park, UK);
- First World Conference on the Mediterranean Diet (July, the 6th-8th, 2016, Milan (Italy);
- Annual meeting of the European Health Psychology Society (August, the 27th, 2016, Aberdeen, Scotland);
- Annual meeting of HEPA Europe and 7th HEPA Europe Conference (September, the 28th-30th, 2016, Belfast).

Furthermore, the conference "The ethics of health incentive programs" has been organized and sponsored by C4H and took place in Munich (19-20 December, 2014).

With regards to publications, three papers have been published during the project, and a special issue of a journal will be issued in January 2017 with the sponsorship of C4H.

Papers published:

- Lena Fleig et al., *Beyond single behaviour theory: Adding cross-behaviour cognitions to the health action process approach*, Br J Health Psychol. 2015 Nov;20(4):824-41. doi: 10.1111/bjhp.12144. Epub 2015 Jun 25.
- Verina Wild et al., *Health incentive research and social justice: Does the risk of long-term harms to systematically disadvantaged groups bear consideration?*, J Med Ethics doi:10.1136/medethics-2015-103332.

- Ralf Schwarzer et al., *Who Benefits from a Single-arm Online Intervention to Improve Dietary Behaviors?*, Public Health Nutrition, doi:10.1017/S1368980016002913.

Paper under review:

- *Sense of community and the perception of the socio-physical environment: A comparison between urban centers of different sizes across* Europe, Under review in the Journal *Social Indicators Research*

Furthermore, a special issue in one of the highest-ranked medical ethics journals, the *Journal of Medical Ethics*, edited by Anca Gheaus and Verina Wild, will be printed on paper in January 2017. Almost all of the papers that will be included are already available online. The publication will be sponsored by C4H. Finally, three paper abstracts have been presented during conferences, and are being elaborated for future publications.

Another very important result of C4H is the partnership with the University College of London (UCL), Centre for Behaviour Change (CBC). The centre was established in 2013 and is led by Prof Susan Michie, a leading international behavioural-science academic. The CBC brings together a range of academic disciplines within UCL (psychology, behavioural science, economics, computer sciences). In addition to conducting research and hosting events (including an annual behaviour-change conference), CBC provides consultancy, training and teaching through a suite of courses.
This partnership links CBC's training and capacity-development content with C4H partner C3's networking skills to create an outreach programme for C4H. The network resulting from the collaboration is the 'CBC Digi-hub in association with Credits4Health'.

The digi-hub was established in the LinkedIn platform (CBC Digi-hub in association with Credits4Health), and has also a dedicated section on UCL CBC's website and works also as a Twitter hashtag (#CBChub). It is composed of over 400 members working primarily in Europe, with a few members from USA, Australia, New Zealand and Hong Kong. These members are digital health and behaviour change professionals representing academic, research, industry, developer, government and other private sector interests.

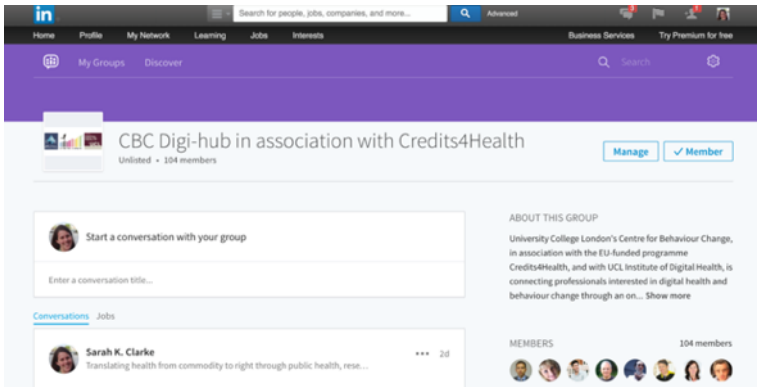



**Figure 15. Screenshot of the digi-hub LinkedIn group**

One of the main objectives of the C4H was to assess the validity and sustainability of the C4H system, and to evaluate the possible commercialization of the C4H system in the European Countries. This was considered crucial since the beginning of the project activities. Indeed, one of the main barriers preventing the adoption of preventive healthcare systems is that they are economically sustainable, so that on one side national healthcare systems are unlikely to invest on them (unless the cost-benefit analysis is really convincing), on the other side private investors are not keen to support them because they are not profitable.

The C4H has thus defined on one side an industrial plan with a sound business plan centered on the business model that seemed more suitable to the Consortium. In particular, the main target customer has been identified in corporates willing to enhance their employees' wellbeing by means of structured wellness programs, and further boost the employees' motivation with specific and targeted incentive schemes, which can be customized on the basis of the corporates' needs. The business plan explores the competitive scenario, the value chain, and the requirements for launching the platform in the market (in terms of both resources and economic investments). Basically, all the information is given to accompany the Consortium in the difficult path that leads a research platform to become a business enterprise.

The other fundamental step has been to accurately define all the steps needed to support the C4H Consortium to shift from a variegated, but mainly research-oriented group, towards an entrepreneurial and market-oriented start-up company.

One of the most important results has been bridging the gap between the research and the market, by setting up all the steps to give maximum market value to the more than 40 foregrounds identified. The first and main step that the Consortium Partners performed is a Master Agreement which represents a binding and useful tool for exploiting the Foreground following a pre-defined strategy aligned with a business-oriented attitude.

Core parts of the exploitation strategy is the incorporation of the Newco (with the identification of place, type of company, and equity allocation amongst the partners), as well as the agreement on the royalties (and their distribution method) for the partners who decide to not take part to the entrepreneurial venture.