Engaging with users and evaluating connected health solutions

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Presentation overview

1. **Background**
2. **What is *Credits for Health*?**
3. **The Consortium**
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1. Background (I)

World Health Organization (WHO)[1] - 2012

Epidemiological context:

- **Non-Communicable Diseases (NCDs)** are the leading cause of death, disease and disability in the WHO European Region.

- **NCDs** account for nearly 86% of **deaths** and 77% of the **disease burden** on health system and on wellbeing, especially in people aged 50 years and older.

- **NCDs** are responsible for many of the **growing health inequalities** that have been observed in many countries, showing a strong socioeconomic gradient and important gender differences.

ACTION PLAN for *Implementation of the Global Strategy for the Prevention and Control of Non-communicable Diseases*

[1]WHO, Action Plan for implementation of the European Strategy for the Prevention and Control of Noncommunicable Diseases 2012–2016, WHO/Europe, (2012)

1. Background (II)

Non-Communicable Diseases (NCDs)

They are long duration and generally slow progression diseases, that are not passed from person to person and are also known as **chronic diseases**.

The **four main types** of **NCDs** are:
- Cardiovascular diseases (like heart attacks and stroke);
- Cancers;
- Chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma);
- Diabetes.

http://www.who.int/topics/noncommunicable_diseases/en/

1. Background (III)

Risk factors – Behaviours

Risk of dying from a NCD

Unhealthy diets

Physical inactivity

Harmful use of alcohol

1. Background (IV)

Top 10 global causes of deaths, 2000
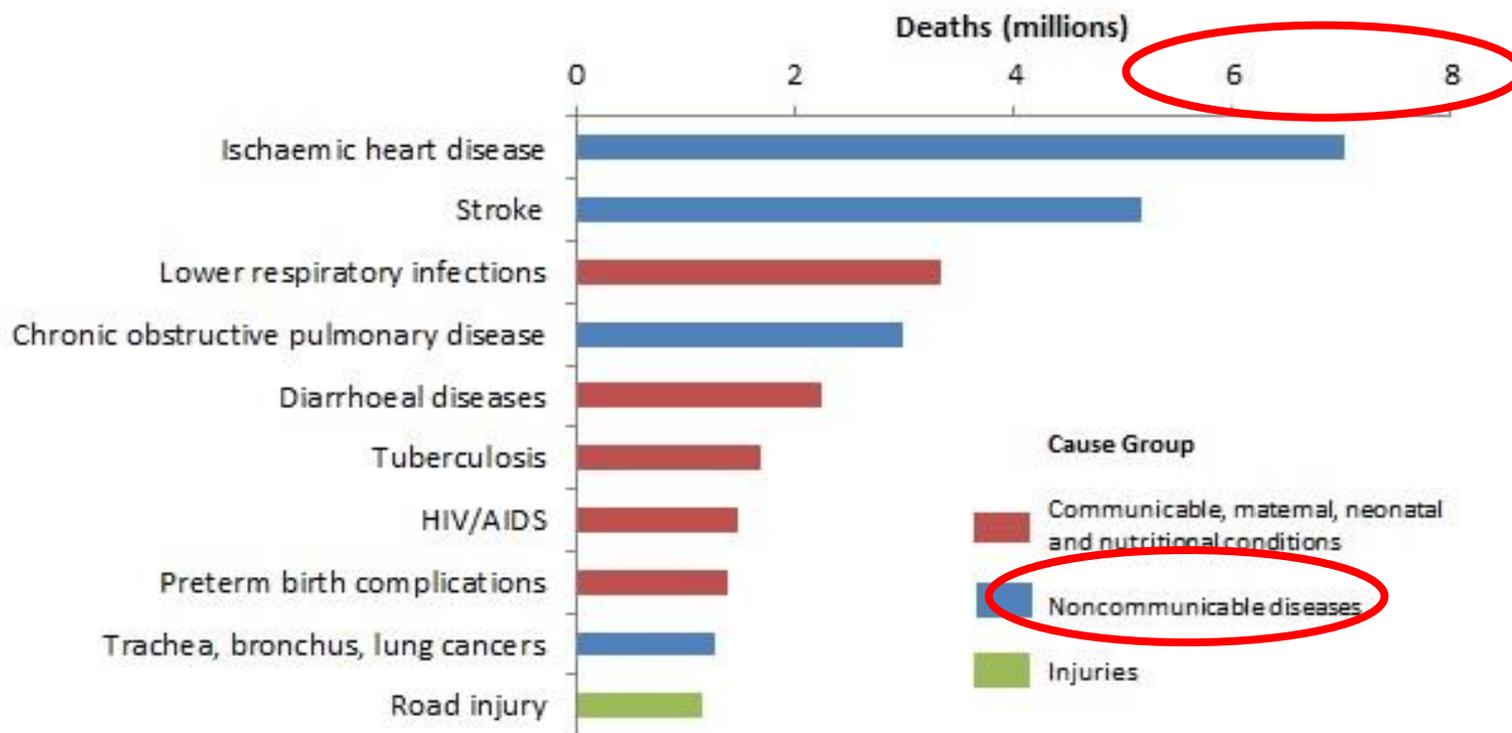
Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2016. Geneva, World Health Organization; 2018.

1. Background (V)

Top 10 global causes of deaths, 2016

Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2016. Geneva, World Health Organization; 2018.

Prevalence of chronic disease-related deaths in developed and developing countries worldwide in 2020
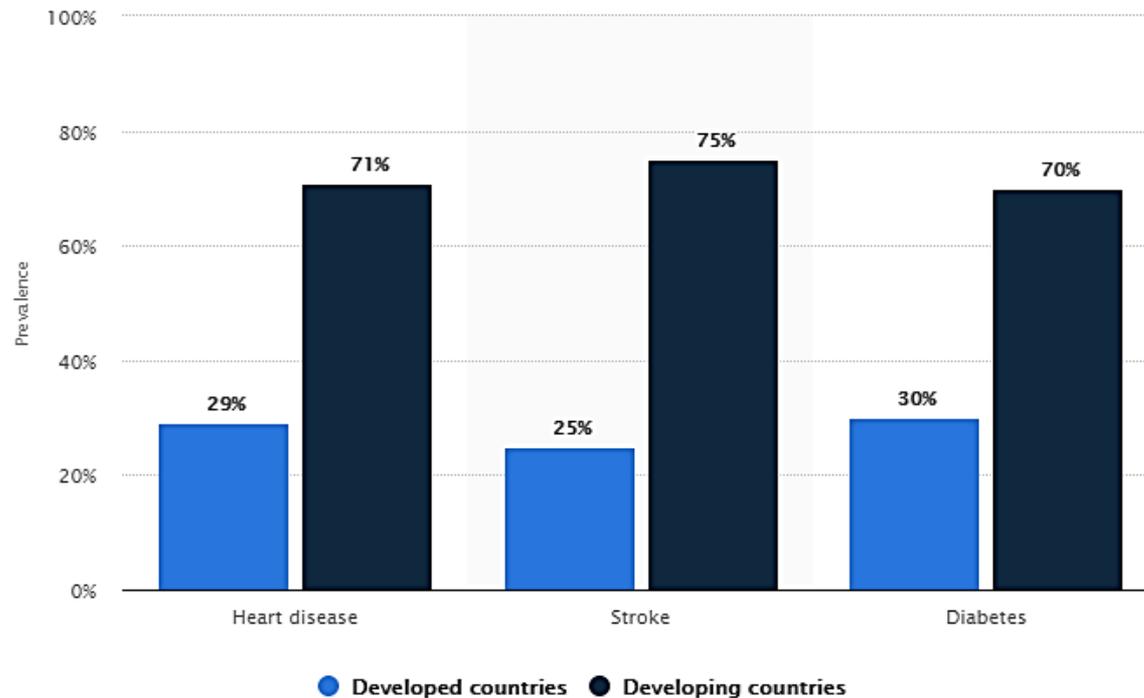
Forecast of the prevalence of CD-related deaths in developed and developing countries worldwide in 2020. Some estimated 70 percent of the diabetes-related deaths in 2020 are projected to occur in developing countries.

Source: © Statista 2018

1. Background (VII)

Seventh Framework Programme (FP7)

FP7 is the short name for the Seventh Framework Programme for Research and Technological Development. This is the EU's main instrument for funding research in Europe and it was run from 2007 to 2013.

- FP7 supports research in selected priority areas.
- FP7 is made up of 4 main blocks of activities forming 4 specific programmes plus a fifth specific programme on nuclear research:
    1. Cooperation
    2. Ideas
    3. Capacities
    4. Nuclear research and train
    5. Joint research Centre

Collaborative research on «HEALTH»: «Credits for Health»

2. What is *Credits for Health* (C4H)?

Project Acronym: Credits4Health

Title: 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.

Contract/Grant agreement number: 602386 – FP7

Period: 01/09/2013 – 31/08/2016

Duration: 36 months

Coordinator: Prof. Maria Luisa Brandi

Grant agreement no 602386

3. The Consortium and participating Countries

- **Italy**
- **Spain**
- **Greece**
- **Germany**
- **United Kingdom**

Coordinating Institution:
University of Florence, Florence (Italy)

4. Goals & Methods (I)

Problem statement: fight the increasing prevalence of lifestyle-related diseases (Non Communicable and Chronic Diseaseas).

Credits4Health **aimed at** DESIGNING, DEVELOPING and TESTING a preventive healthcare system, consisting in an **ICT Platform in order to:**

- Reduce sedentary behaviour

- Enhance the level of physical activity

- Foster the adoption of a healthy dietary lifestyle, with particular focus on the Mediterranean diet.
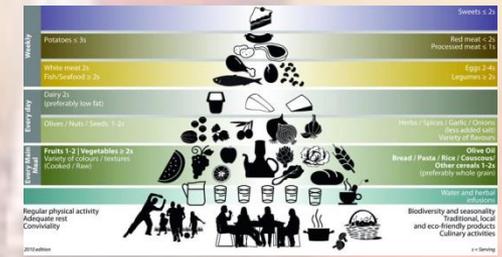
4. Goals & Methods (II)

The **ICT Platform:**

Homepage

«My profile» status (credits, ranking, progress)

Credits system section

Nutritional and PA information pages («Wiki» pages)

Nutrition section

Physical activity (PA) section

Forum section
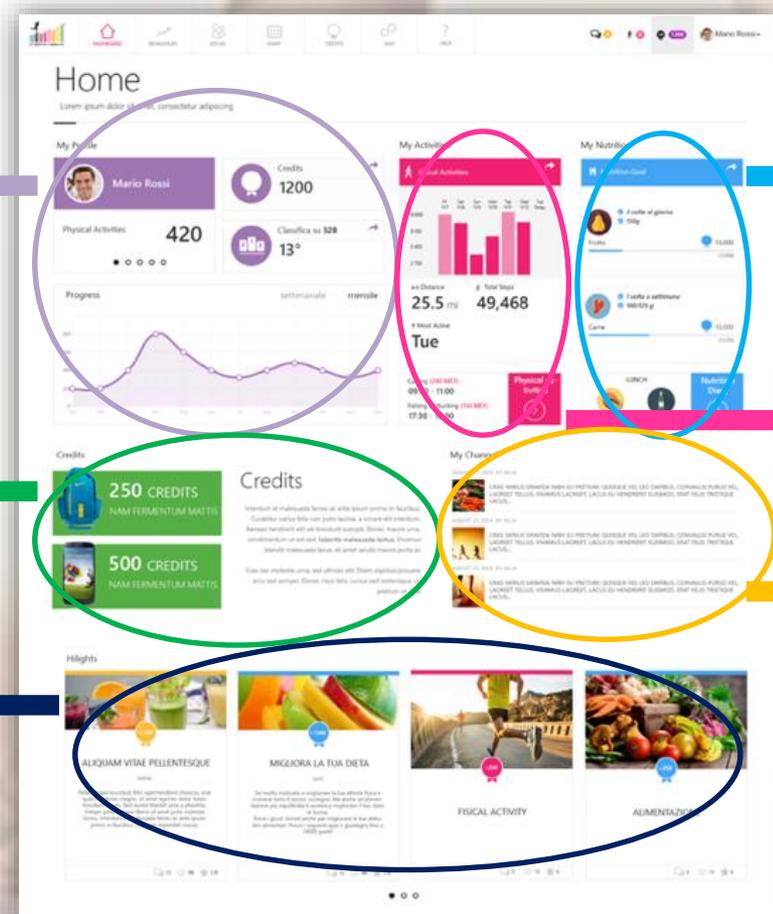
5. The C4H Concept (I)

➤ *People empowerment*

A multi-stakeholder approach in which **people play the main role**, being involved in improving their health status and being responsible for their well-being.

C4H supports people to be the authors of their own health.

➤ *[Nudge concept](#)*

Try to **move people** in certain directions, **preserving the liberty** to choose what one likes (*"Libertarian paternalism"*).

C4H explicit aim is to **gently support** people to pursue a healthy lifestyle without any form of coercion nor forbidding any possible option.

The Nudge Theory
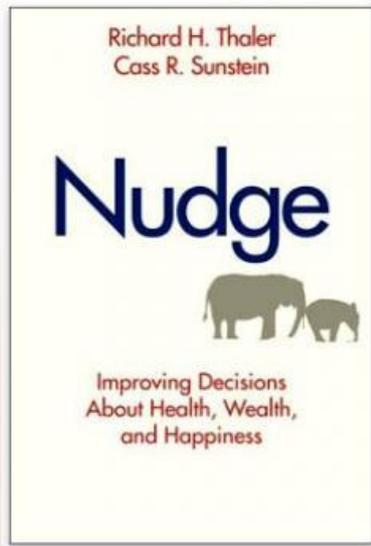
Richard Thaler and Cass Sunstein defined their concept as:

*«A **nudge***, as we will use the term***, is any aspect of the choice architecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives***. To count as a mere nudge, the intervention must be easy and cheap to avoid. Nudges are not mandates. **Putting fruit at eye level counts as a nudge. Banning junk food does not***.»*

Richard Thaler – 2017 Nobel prize in Economics

Examples of C4H support. "WIKI" content on nutrition

5. The C4H Concept (IV)

➢ *Personalized paths*

The interventions delivered through the platform deal with three major domains: psychology, nutrition, and physical activity.

1. **Psychological intervention** aimed to motivate them in improving their behaviours related to both nutrition and physical activity.

2. **Nutritional intervention** aimed to improve dietary behaviours, within the context of the Mediterranean Diet.

3. **Physical activity intervention** aimed to enhance the level of daily physical activity.

5. The C4H Concept (V)

Example of *Personalized paths.* Nutrition Goal setting in 3 steps
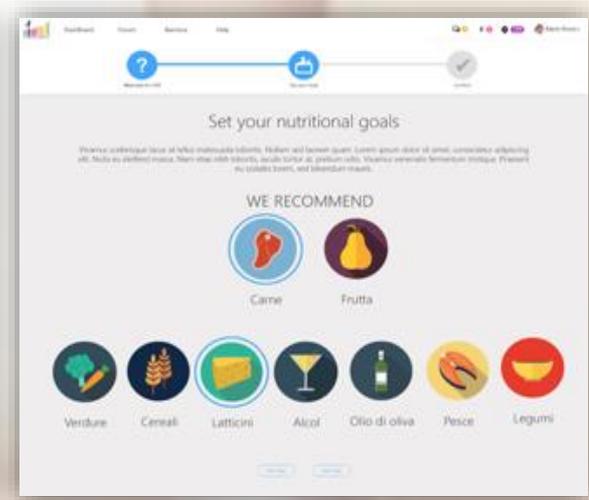
5. The C4H Concept (VI)

Example of *Personalized paths.* The PA and nutrition calendars
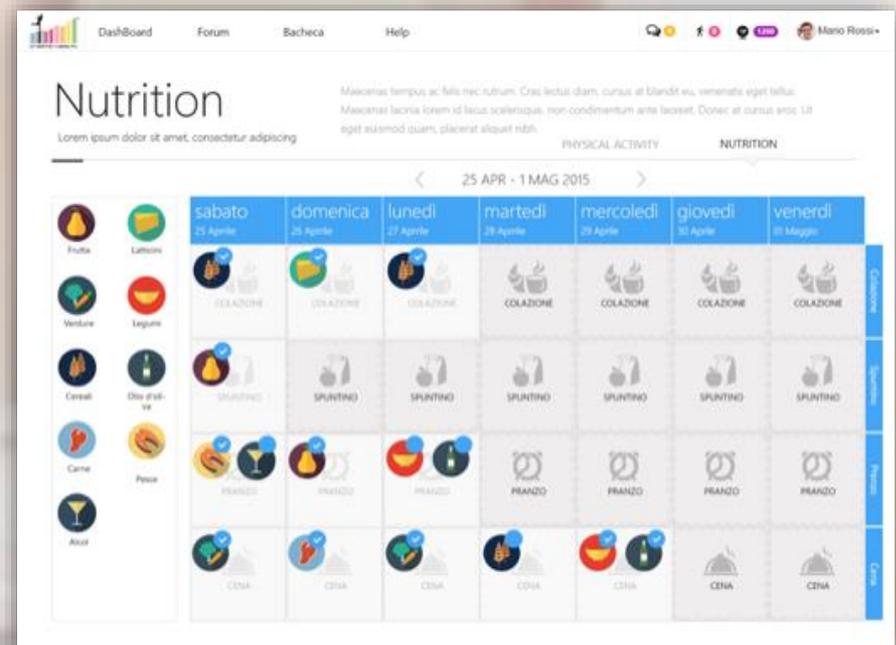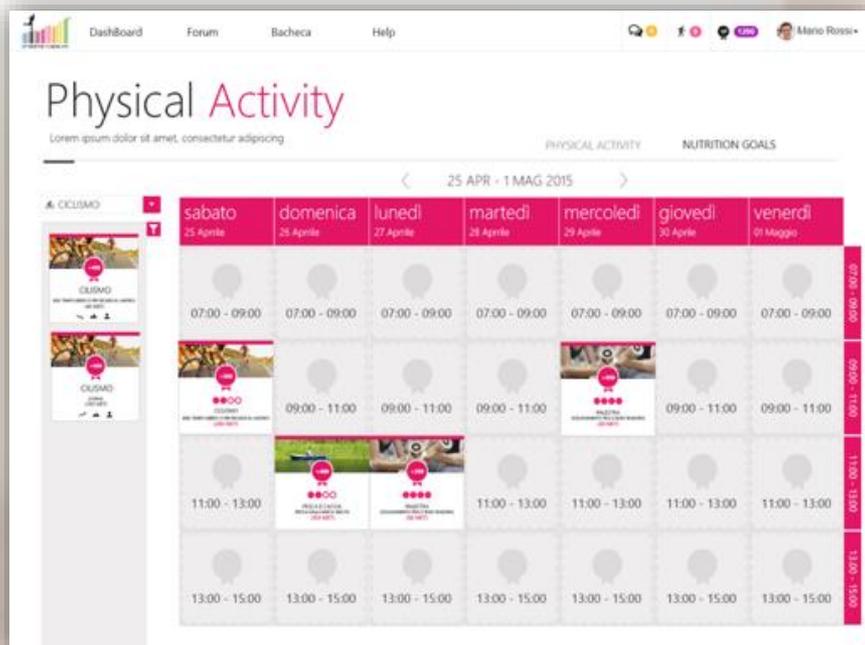
➤ *Credits system*

A **multi-stakeholder rewarding system** consisting of discounts on goods and services related to health, nutrition, social and leisure activities, etc.

C4H approach uses *positive incentives*, that are used to promote specific practices (e.g. subsidizing healthy food to facilitate their consumption).

Examples of the Credit System. Three pages from the Rewards section
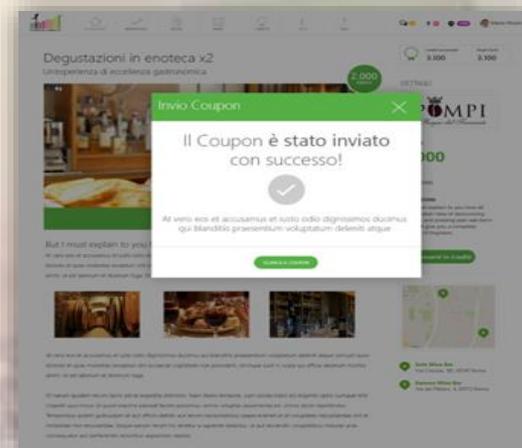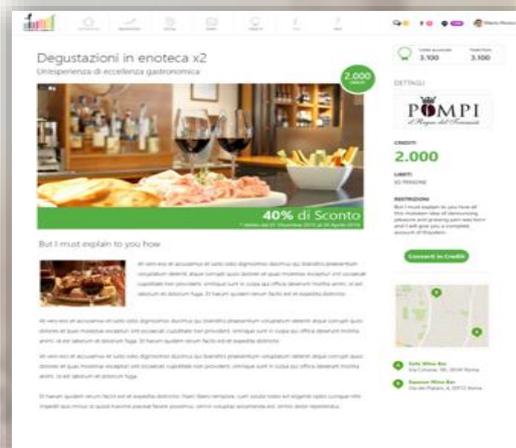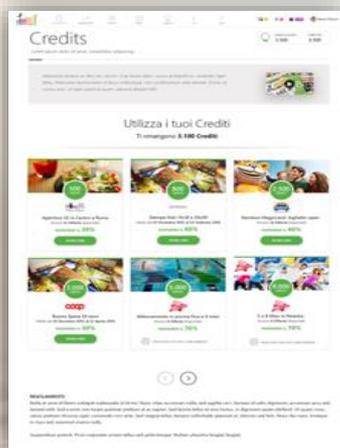
5. Field-tests and Target Users (I)

A phased approach. Complex web-based interventions like C4H need a phased approach to gradually test each component of the final system. C4H is designed on the basis of a such a framework:

- **Two pilot studies** aiming at testing the proposed system, the interventions and the evaluation parameters (Pilots 1 and 2);

- **A Randomized Controlled Trial (Pilot 3)**, aiming at assessing the effectiveness of the intervention (platform + credits) with respect to the objectives of the research study.

The target users of the final product are European citizens willing to improve or maintain their health status.

The product have been tested on a total of **2,700 participants** recruited in **4 Euro-Mediterranean study areas** (Florence and Salento in Italy, Girona in Spain, and Pylos Nestoras in Greece).

6. Field-tests and Target Users (II)

Three Studies involving 2,700 people in four Study Areas:

1. City of Florence (Italy)   300,000 pop.   39.54 square miles
2. Region of Salento (Italy) 1,500,000 pop. 2,057 square miles
3. City of Girona (Spain)   97,000 pop.   15.11 square miles
4. Kalamata municipality (Greece) 69,849 pop. 213/170 square miles

6. Field-tests and Target Users (III)

Pilot studies

	Pilot 1	Pilot 2	Randomized Controlled Trial
High-level objectives	• Evaluate the effectiveness of the personalized paths (interventions) and refine them in Pilot 2. • Assess the platform usability and actual usage to refine the platform in pilot 2. • Assess the drop-out rate to tackle it in Pilot 2.	• SAME GOALS OF PILOT 1 • Introduce and assess the credits system to refine it in Pilot 3.	A Randomized Controlled Trial to: • Assess the effectiveness of the personalized paths in enhancing participants' physical activity and nutritional habits. • Assess the effectiveness of the credits system.
Duration	3 months	3 months	8 months
Study procedures and main features	• Recruitment (Incl/excl. criteria assessment) • Baseline assessment • Platform activities • Final assessment	• Recruitment • Baseline assessment • Platform activities + credits system • Final assessment	• Recruitment • Baseline assessment • Platform activities + credits system • Final assessment

6. Field-tests and Target Users (III)

- Have been β-test platform studies (*Open label studies*), necessary to test and improve the platform functionalities that have been used later for the RCT design.

- **Pilot 1**
  - Recruitment period: December 2014 (Italy); until Middle March 2015 (Greece).
  - Monitoring period on the platform lasted 2 months for each area.
  - At the end of Pilot 1 study, participants were offered the opportunity to enter into Pilot 2 study
  → A total of 204/460 subjects (44%) were still interested to continue.

- **Pilot 2**
  - Recruitment period: Middle May 2015 (Italy); until end July 2015 (Greece).
  - Monitoring period on the platform should have been lasted 2 months for each area, but it went on for 2 additional months (4 months in total).
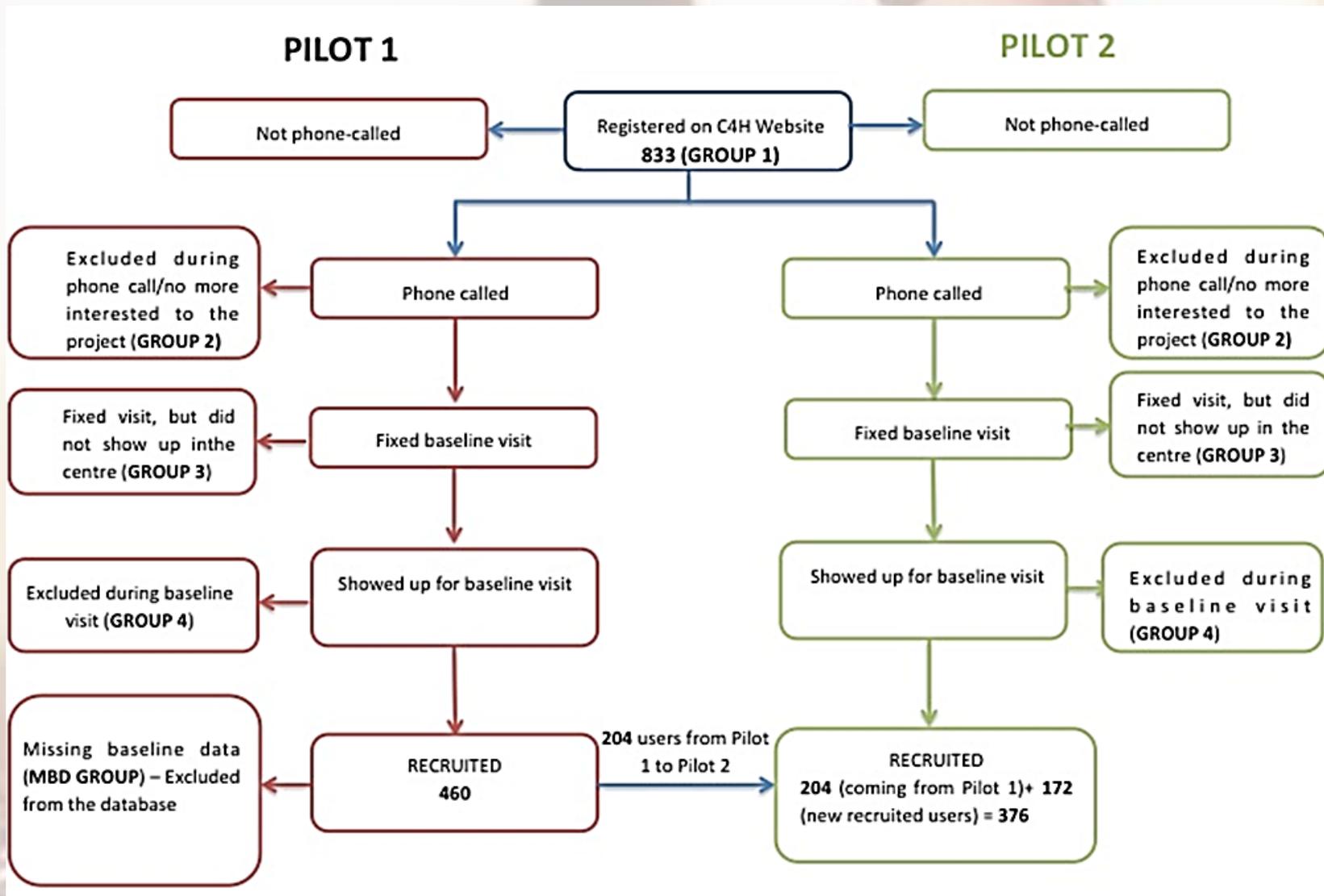
PILOT 1 & PILOT 2 (III)

Baseline	PILOT 1 (N= 460)	PILOT 2 (N= 376)
«Screening failures»	90 (19.6%)	130 (34.6%)
Study group	370	246
Mean age (of the Study Group)	42.82 (S.D. ± 10.24)	42.01 (S.D. ± 9.99)
Gender (of the Study Group)	M 142 (28.4 %) F 228 (61.6 %)	M 110 (44.7 %) F 136 (55.3 %)
Country (of the Study Group)	Italy 126 (34.1 %) Spain 140 (37.8 %) Greece 104 (28.1 %)	Italy 82 (33.3 %) Spain 93 (37.8 %) Greece 71 (28.9 %)

Platform Homepage

6. Field-tests and Target Users (IV)

RANDOMIZED CONTROLLED TRIAL (1)

- **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 behaviours .
    - Recruitment period: October 2015 (Italy); until January 2016 (Greece).
        → Recruitment procedure included also Blood tests.
    - Launch of the platform: December 2015.
    - Monitoring period on the platform lasted **6 months** for each area.

- The **block-randomized design** has been developed using an automated algorithm to ensure balanced distribution of participant characteristics across the intervention and control groups:
    ➢ Intervention group → DYNAMIC PLATFORM
    ➢ Control group → STATIC PLATFORM

RANDOMIZED CONTROLLED TRIAL (2)

Study design

Registered on C4H Website (GROUP 1): 2956

Not called by phone: 416

Phone called: 2540

Excluded during phone call (GROUP 2): 330

Fixed baseline visit at the centre: 2210

Fixed visit, but not come to the centre (GROUP 3): 118

Come to the centre for the baseline visit: 2092

Excluded during baseline visit at the centre (GROUP 4): 28

RECRUITED 2064

Screening failures (GROUP 5): 499

Study group (RANDOMISED): 1565
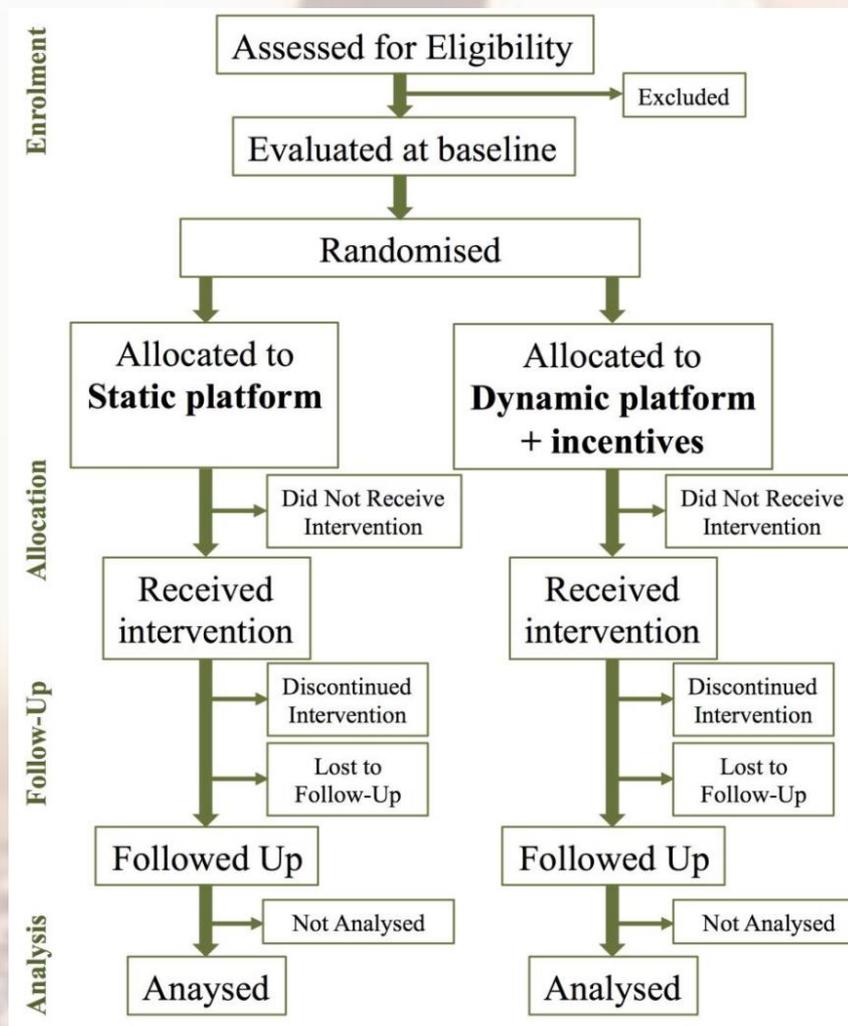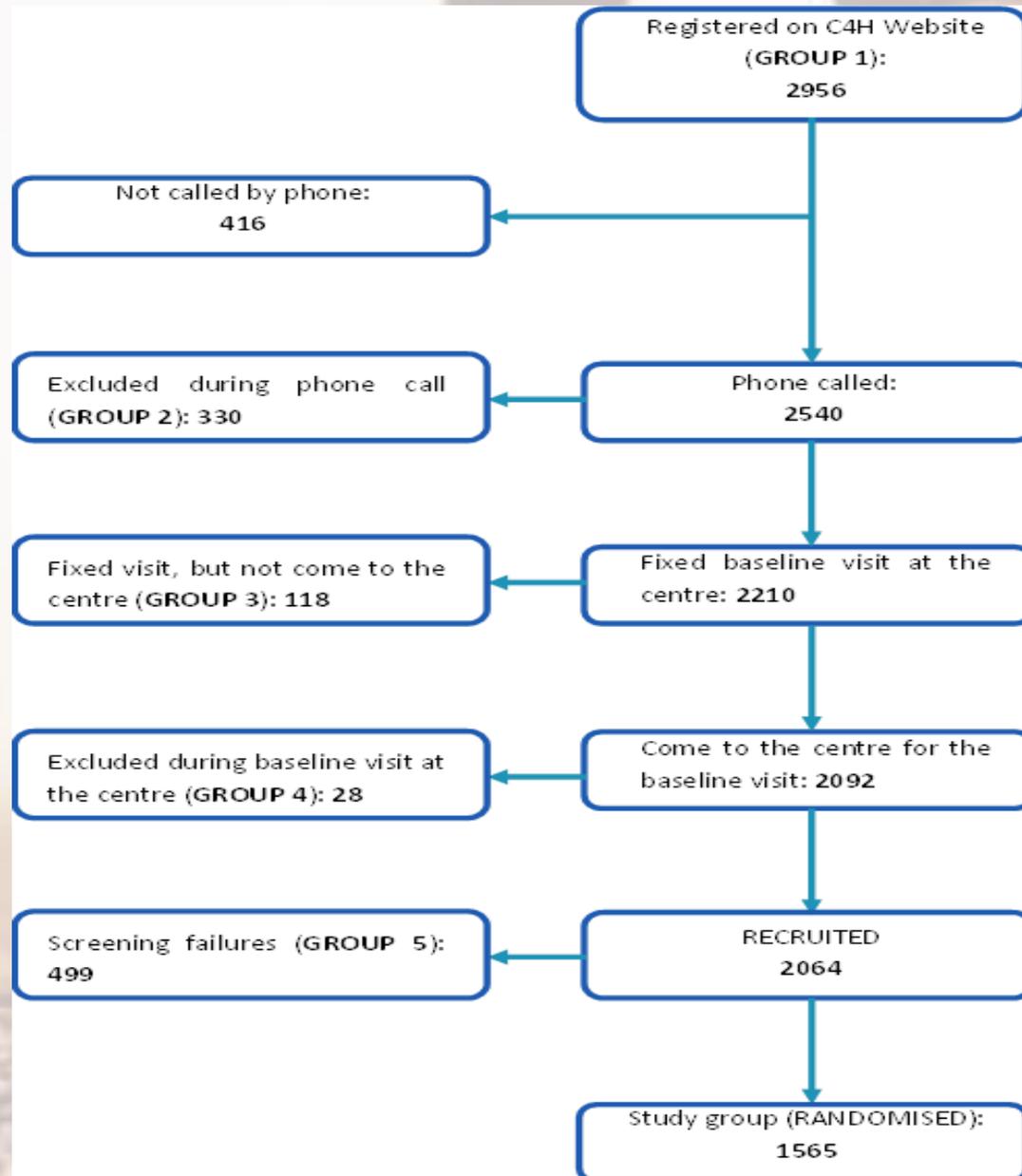
RANDOMIZED CONTROLLED TRIAL (4)

Baseline	RCT (N= 2064)
«Screening failures»	499 (24.2%)
Study group	1565
Mean age (of the Study Group)	40.9 (S.D. ± 11.5)
Gender (of the Study Group)	M 616 (39.4 %) F 949 (60.6 %)
Country (of the Study Group)	Italy 656 (41.9 %) Spain 628 (40.2 %) Greece 281 (17.9 %)

RANDOMIZED CONTROLLED TRIAL (5)

Baseline evaluation

	Italy (%*)	Spain (%*)	Greece (%*)	Total (%*)
Baseline Visit	656 (41.9%)	628 (40.1%)	281 (17.9%)	1565 (100%)
PSY Q	654 (41.8%)	628 (40.1%)	280 (17.9%)	1562 (99.8%)
NUT Q	655 (41.8%)	628 (40.1%)	280 (17.9%)	1563 (99.8%)
PA Q	656 (41.9%)	628 (40.1%)	281 (17.9%)	1565 (100%)
Blood tests	653 (ALL the parameters) (41.7%)	561 (Tot. Col. + Glycemia + Glycated Haemoglobin + Tryglicerides) (35,8%)	252 (ALL the parameters) (16.1%)	1466 (93,7%)

*Percentage calculated in relation to the effective total number of the Study group (N=1565).

Final evaluation

	Italy (%*)	Spain (%*)	Greece (%*)	Total (%*)
Final Visit	465 (47.4%)	347 (35.4%)	131 (13.4%)	943 (96.2%)
PSY Q	331 (33.8%)	298 (30.4%)	95 (4.6%)	724 (68.8%)
NUT Q	321 (32.7%)	297 (30.3%)	40 (4.1%)	658 (67.1%)
PA Q	311 (31.7%)	212 (21.6%)	38 (3.9%)	561 (57.2%)
Blood tests	418 (42.6%)	0 (0%)	117 (11.9%)	535 (54.5%)

*Percentage calculated in relation to the effective total number of the Study group (N=980).

7. Main results (I)

C4H results can be attributed to the following main categories:

> ➢ Technological results

> ➢ Psychological results

> ➢ Scientific results (Nutritional data, Physical Activity data, Anthropometric data)

> ➢ Communication results

> ➢ Ethical results

7. Main results (II)

> **Technological results:**

The main technological results pertain to the design and development of the C4H system, and in particular of the ICT platform.

PILOT 1 & PILOT 2:
- served to set up the real Dynamic platform to be tested in RCT.

- People experienced some troubles in the interaction with the platform
  - → Technical problems have been solved and the platform has been implemented in its functionalities.

RCT:
- New tools for the evaluation of the users have been created (i.e. Credits system).

- Algorithms have been designed for structuring the interventions directed at the users.

7. Main results (III)

> **Psychological results (1):**

- increased in motivation to engage in healthy eating and regular exercise (i.e. intention).

- Increased of self-confidence to change eating behaviour and to enhance the level of physical activity (i.e. self-efficacy).

- Increased of positive outcome expectancies as a result of engaging in a healthy lifestyle.

Specific RCT results:

At final assessment point, **Dynamic platform users** reported

- to perceive more positive outcomes as a result of eating healthily and exercise more,

- to be more confident in their ability to change eating and PA behavior,

- to be more motivated to change their behavior,

than Static platform users.

> **Psychological results (2):**

Stage transitions: Percentage of participants who progressed to a higher stage of engagement in terms of their Mediterranean diet separated for static (left panel) and dynamic platform users (right panel).

Schwarzer R et al., Final report
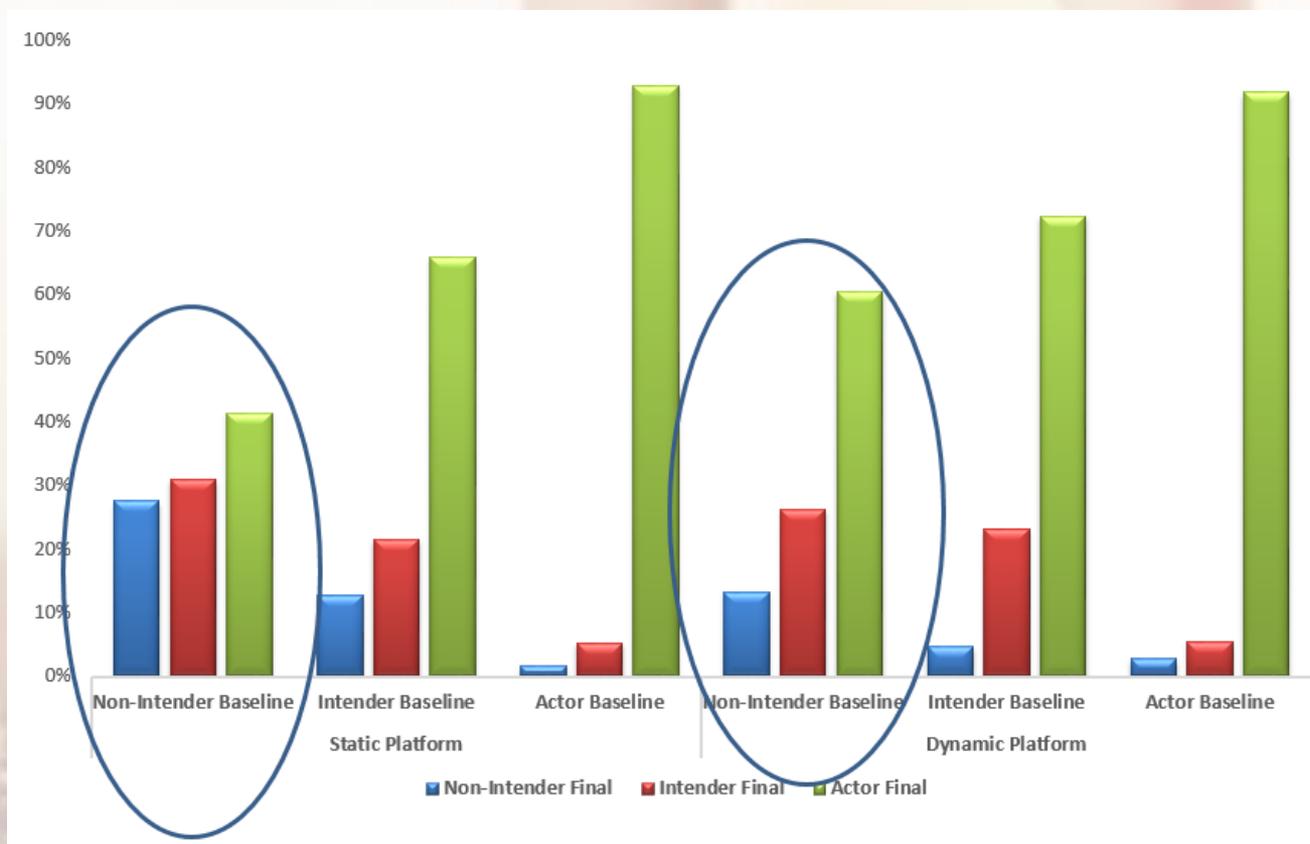
➢ **Psychological results (3):**

Mean level changes in self-reported physical activity under two experimental conditions, moderated by sex. Dependent variable is physical activity (GPPAQ sum score) at three points in time with a range from 0 to 8 (N = 638 adults with complete longitudinal GPPAQ data).

Schwarzer R et al., Br J Health Psychol. 2018
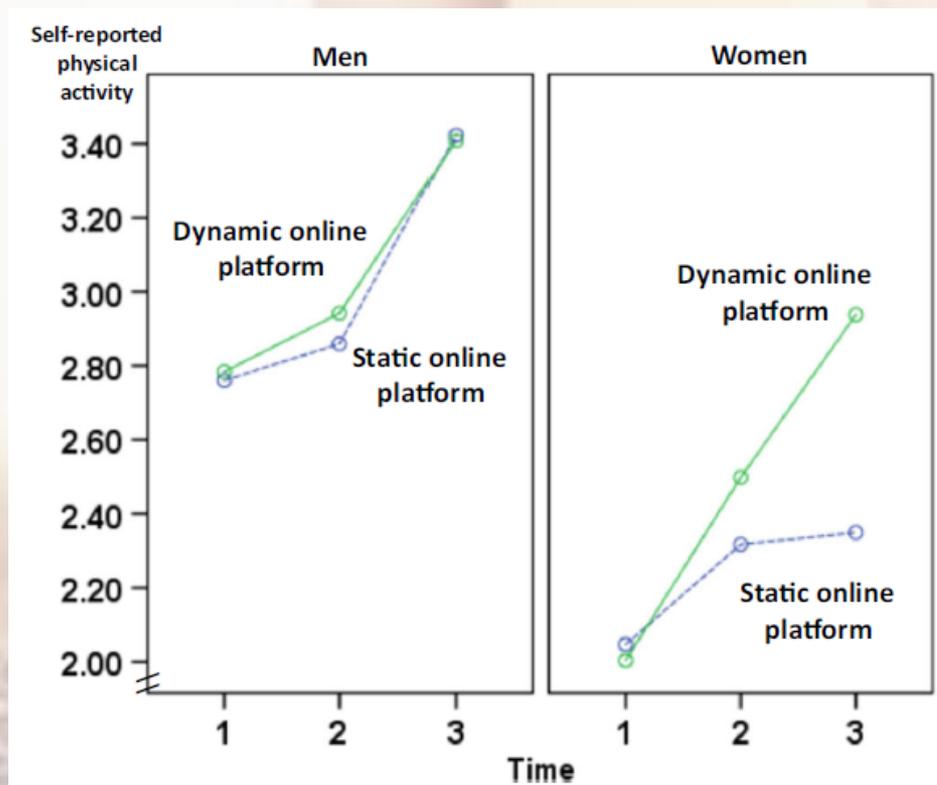
7. Main results (IV)

➢ **Scientific results – Nutritional data (1):**

PILOT 1 & PILOT 2:

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

PILOT 1	PILOT 2
Increase: ✓ Fish ✓ Fruits ✓ Vegetables ✓ Legumes ✓ Unsalted nuts and seeds ✓ Regular olives ✓ Eggs	Increase: ✓ Legumes ✓ Unsalted nuts and seeds Decrease: ❖ Sugar sweetened beverages ❖ Red meat

Scientific results – Nutritional data (2):

RCT:

✓ Increased in the adherence to the C4H recommendations, in terms of increasing the healthy food groups consumption and decreasing less recommended food groups consumption.

✓ Improved the adherence to the Mediterranean Diet (measured with a Mediterranean Diet score).

Dynamic platform users		Static plaform users	
Increase:	Decrease:	Increase:	Decrease:
✓ Olive oil	❖ Other fats and oils	✓ Fish	❖ Potatoes
✓ Fish	❖ Potatoes	✓ Fruit	❖ Cereals
✓ Fruit	❖ Cereals	✓ Vegetables	❖ Pizza
✓ Vegetables	❖ Pizza		
✓ Legumes	❖ Sugar sweetened beverages		
✓ Wholegrain cereals	❖ Commercial sweets or pastries		
✓ Water	❖ Dairy products		
	❖ Red meat		
	❖ White meat		
	❖ Highly processed products		
	❖ Red wine		
	❖ High alcohol beverages		
	❖ Fast food and junk food		

7. Main results (V)

> **Scientific results – Physical Activity data:**

PILOT 1 & PILOT 2:

The PA 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.

RCT:

> Increased of the PA level (self-estimation and PA tracker assessment), supported by both platforms.

> C4H platform has been appealing especially for inactive people that improved both their number of steps and accesses to the platform itself.

7. Main results (V)

> **Scientific results – Anthropometric data & Blood Test data:**

PILOT 1 & PILOT 2:

Regarding the **total population** the results show that all the anthropometric parameters (weight, BMI, Fat Mass, Fat Free Mass, Waist Circumference), have been significantly changed from the beginning to the end of the Pilot 1 study period **(p< 0.01)**, but in the Pilot 2 this trend is not confirmed.

RCT:

> Regarding the **total population** the results show that all the anthropometric parameters have been significantly decreased from the beginning to the end of the study, with the exception of the Fat free mass (FFM), that is increased **(p< 0,01).**

> Regarding the **total population** the results show that Tot. cholesterol, HDL, LDL and Fasting plasma glucose have been significantly decreased from the beginning to the end of the study **(p< 0.01).**

## ➤ **Scientific results – Anthropometric data in the RCT:**

Anthropometric data Pilot 3: baseline vs final
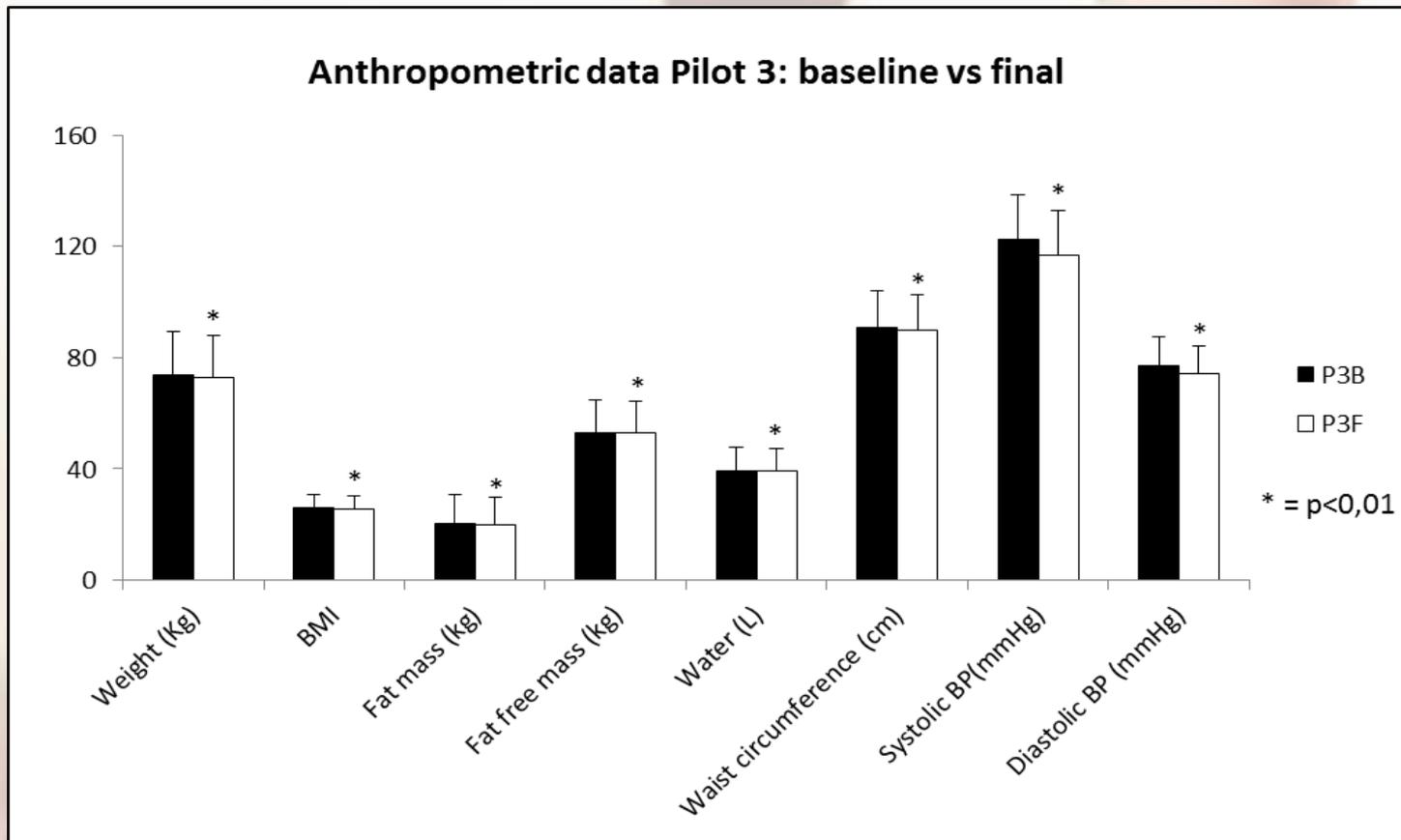
Figure (RCT - Anthropometric data of Total population
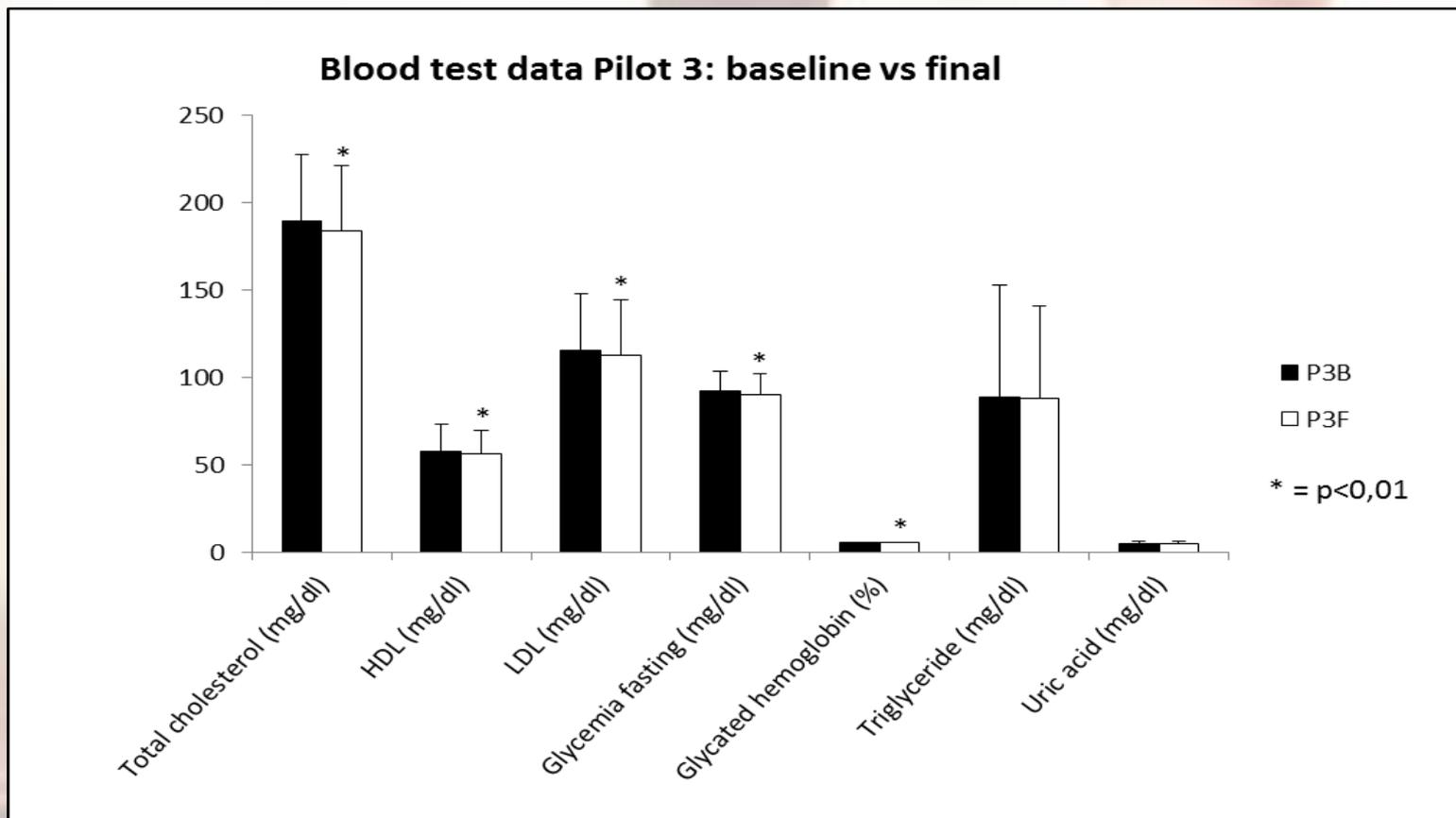
Figure RCT – Blood test data of Total population

7. Main results (VI)

➢ **Communication results (1):**

- **First official communication of the C4H project** has been the Launch Press Conference in Rome (Italy), at the presence of the *Italian Health Minister* Beatrice Lorenzin (December 2014).

- 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, press, newspapers, radio).

- **Organization in the areas of the study of events** dedicated to physical activity and nutrition, and sponsored by C4H.

Communication results (2):

C4H Event in Florence:

Florence – Piazzale Michelangelo, 07th July 2016
«Pedalando con FIRMO»

https://www.youtube.com/watch?v=Wkwy46IwE4Y

C4H Event in Girona:

Girona – 21st May 2016
«Girona per la salut»

https://www.youtube.com/watch?v=OpA99at3meM

Links to major press releases etc.
http://www.credits4health.eu/press_review/Press_Review_INT_oct_16.pdf

8. Ethical issues (I)

Ethical approval

Interventional study for *primary prevention*:

- C4H study is an *intervention with insurance coverage*.

- Legally, an *«Intervention study»* refers ONLY to pharmacological studies (for secondary prevention).

- C4H is validated by an «Intervention study» (RCT), that focused on Good Clinical Practices (primary prevention).

Credits system:

- No credits nor any other form of rewards (points or whatever) have been assigned to subjects in exchange for their participation to the studies.

- The allocation of credits depended exclusively on participants' achievements of Good Clinical Practices.

8. Ethical issues (II)

Achievements of personal goals are self-reported

Self-reporting arises the problem of the report truthfulness

Linear trend
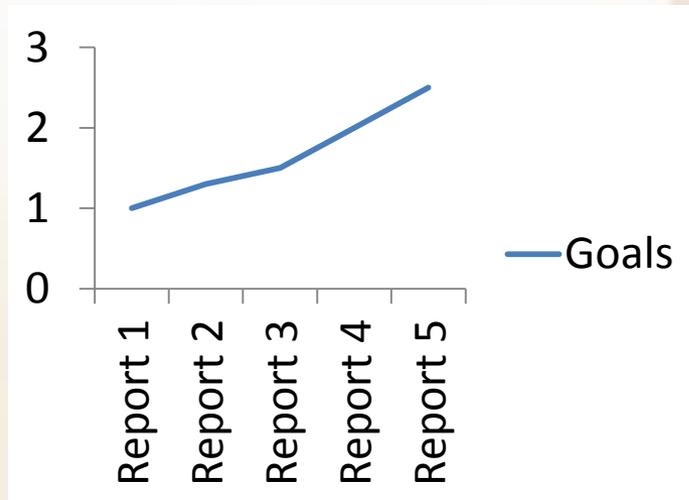
Erratic trend
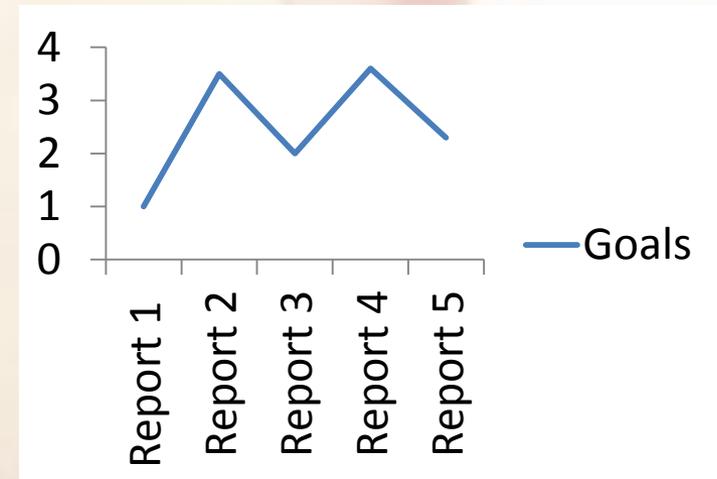
Solution is the Big data analysis:
The future is the use of huge amount of data (that are self-reports and feedbacks from users) in order to create a self-mantaining system in which, through specific algorithms and internal analysis, credits will be assigned automatically and basing on the truthfulness of the answers.

9. Evaluation and engagement of users

C4H: double platform

Evaluation platform:
- behind the users' dashboard.
- For the collection of big data.

Engagement platform:
- For users' interaction and involvement

Inputs (medical data, psychological, nutritional and PA assesments)

UNIQUE PLATFORM → Profiling → USERS

Outputs
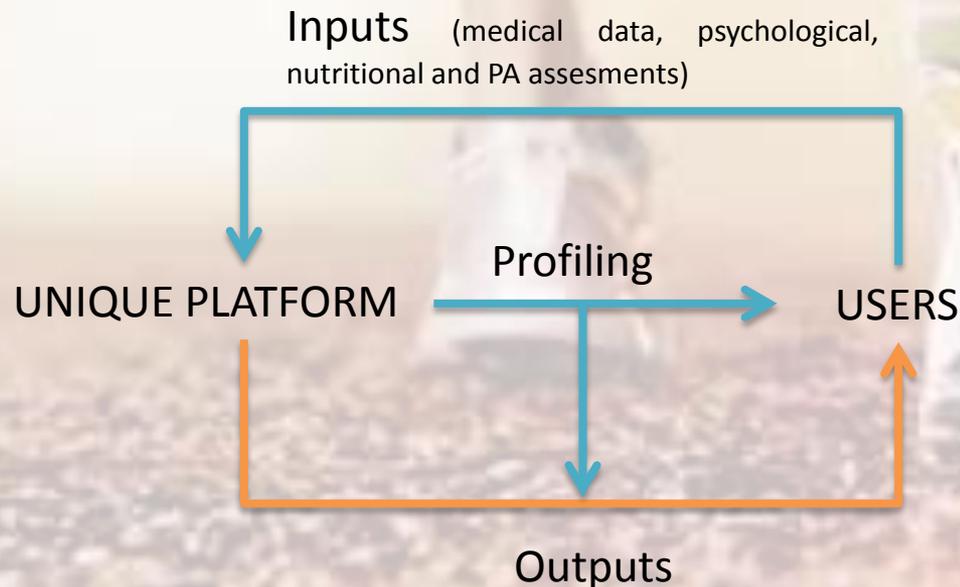
10. Future perspectives

- Semplify data entering.

- Increase data amount (big data analysis).

- Transition from project for Secondary prevention to Primary prevention: importance of Regional projects in order to involve subjects without a full-blown disease.

- Involvement of the Healthcare system, both public and private.

http://www.credits4health.eu/

Thank you for your attention!