

Protocol title:

Is Allen Carr's Easyway to Stop Smoking Programme superior to Smoking Cessation service delivered by Quit.ie? a randomised controlled trial

Protocol Acronym:(ACESCQ)

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Version 2

- Funded by DOH Lottery Fund
- Allen Carr Easy Way to stop Smoking will fund their treatment limb.
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STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the EU Directive 2001/20EC on Clinical Trials and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

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Principle Investigator: Professor Luke Clancy

Co-Investigators: Ms Sheila Keogan, Specialist Nurse Practitioner, and Dr Kate Babineau PhD, post-doctoral research fellow.

Project summary

The Framework Convention for Tobacco Control (FCTC) is the first binding public health treaty of which 179 parties including Ireland have ratified mandates, among other Tobacco Control interventions; the service for Treatment of Tobacco Addiction is instituted by all parties.

In this regard there are effective and cost effective treatments available. However one widely-used non-pharmacological method, the Allen Carr (AC) Easyway to Stop Smoking, purports to be very successful but has not yet been directly compared to established validated treatments through a trial. There is wide-spread support for the efficacy of the AC method though without peer-reviewed evidence of its performance, it cannot be introduced as a formally approved treatment in public services.

In this proposed randomised controlled trial we will compare the AC method with 'Quit.ie' services, a widely used public service designed to enrol people on a quit programme using the internet, the phone, and one-on-one support based on the needs of individual clients.

Participants will be recruited by advertisement and randomly assigned to AC or Quit.ie. AC will be delivered by AC specialists, Quit.ie will be provided as per HSE guidelines and materials. The effectiveness of each method will be tested at months 1, 3, 6 and 12 in a bid to establish if there is equivalence in success rates.

GLOSSARY OF ABBREVIATIONS:

Abbreviation	Term
DOH	Department of Health
TFRI	TobaccoFree Research Institute Ireland
DIT	Dublin Institute of Technology
FCTC	Framework Convention for Tobacco Control
AC	Allen Carr Easy Way to Stop Smoking
RCT	Randomised Controlled Trial
EU	European Union
BI	Brief Intervention
HSE	Health Service Executive
SC	Smoking Cessation
HCP	Healthcare Professionals
NRT	Nicotine Replacement
NCPE	National Centre for Pharmacoeconomics
CO Monitor	Carbon Monoxide Monitor
TQD	Target Quit Date

Rationale & background information

Ireland is acknowledged to be one of the world leaders in tobacco control interventions. In keeping with this status and history, the former Minister for Health Dr James Reilly has declared that Ireland will be Tobacco Free by the year 2025. Smoking Cessation (SC) is key in achieving the 2025 target.

There are a variety of established, proven-successful treatments for tobacco addiction and smoking cessation including brief intervention by a doctor or other Healthcare Professionals (HCPs), psychological support, and pharmacotherapy including nicotine replacement therapy (NRT), Varenicline and Bupropion. The success rates achieved are variable but rarely are better than 20% quit at 12 months and often less than this.

It is acknowledged that many of the available services are limited in scope when it comes to reaching disparate populations. This is due to an inadequacy of resource allocation, lack

of training and commitment among HCPs, and the limitations of present treatment methods (1). Recent efforts have been made to improve the reach and impact of smoking cessation services including the implementation of web and social-media based interventions (e.g. Quit.ie), the development of mobile apps, and the adoption of alternative or ‘holistic’ treatment approaches such as hypnotherapy, laser therapy, and acupuncture. These new approaches are expected to prove to be a positive step. However, they lack consistent scientific proof of efficacy.

Allen Carr’s “Easyway To Stop Smoking” method has become increasingly popular since 1985, advertising a 90% 3-month success rate and 51% 12-month success rate and claiming to have “cured at least 10 million smokers”. The basis of the method is still unclear in terms of cessation interventions that are understood. It does not include pharmacotherapy and no drugs are used. It is delivered at a 5-hour workshop session, during which participants are encouraged to smoke in order to reflect on their reasons for smoking. While numerous celebrity endorsements advertise the success of the programme, it has yet to be submitted to suitable independent examination(2). In the Irish context, the AC programme has treated 12,000 over the past decade. Despite its widespread popularity and use, there has been virtually no empirical research on the efficacy of the AC Easy Way method.

Prescribed medications for smoking cessation such as Nicotine Replacement Therapy (NRT), Bupropion, and Varenicline have a high level of proven success in previous scientific studies(3). Varenicline is a licensed treatment for use as smoking cessation aid in the USA and the European Union, and is widely recommended in many national guidelines(4). TFRI aims to explore the efficacy of Allen Carr’s Easyway to Stop Smoking programme. We have recently completed a pilot study of a hospital based SC clinic using current best practice which shows promise. We have discussed the Allen Carr project with other experts in the field; Prof Michael Barry, National Centre for Pharmacoeconomics, NCPE Ireland, Prof dr. A. Dijkstra, University of Groningen, Prof Linda Bauld, Deputy Director of the UK Centre for Tobacco and Alcohol Studies - all of whom recognise the need and usefulness of assessing ACs method.

Study goals and objectives

The project objectives are:

1. Assess the relative effectiveness of the Allen Carr's Easy Way to Stop Smoking programme against Quit.ie
2. Validate Quit status at 1, 3, 6 and 12 months for each treatment group.
3. To measure the continuous abstinence rate.

Study Goals:

- Provide the evidence base for policy makers with regard to smoking cessation treatments which are suitable for public financing.
- Improve awareness and confidence in known smoking cessation treatments

Study Design

Population: Healthy daily smoking adults aged over 18years.

This project is a randomised controlled trial which will test the 12 month smoking cessation success rate of the Allen Carr Easyway against standardized smoking cessation service with the use of standard care treatment of tobacco dependence. Participants for the study will be recruited through advertisements in newspapers, partnering with healthcare organizations, and other public postings including social media networks. This approach to recruitment is commonly used in RCT studies of smoking cessation(5). Potential participants will be invited to phone in and answer a series of pre-screen questions.

Inclusion criteria:

1. Smokers over 18yrs,
2. Smokes 5 or more cigarettes a day,
3. Is able and willing to attend all workshops and clinics as set out in the protocol.
4. All subjects will give informed consent
5. Have good knowledge of English- because the AC treatment is delivered in English.

Exclusion criteria:

1. Participants undergoing treatment for alcohol or illicit drug abuse
2. Participants diagnosed with acute cardiac or respiratory conditions.
3. Participants with a diagnosed serious psychiatric illness
4. Participants under the age of 18yrs
5. Participants with a poor knowledge of English.

All ineligible participants will be given brief intervention and details of where they can find treatment and support for treatment of tobacco addiction.

If eligible, individuals will be randomly allotted to either:

- 1) The Allen Carr programme
- 2) The Quit.ie service

The numbers needed to treat have been estimated at 279 (i.e. 139 in each treatment arm) to answer the question ‘Is AC Easyway superior to care delivered by Quit.ie?’

The assumption for attrition in these studies is well known, and allowance for this has been made in the subject numbers thought to be required.

Quit rates for each group were predicted as:

- Allen Carr 25%
- Quit.ie 12%

An allocation of 1:1 was selected. With 80% power and two-sided significant level of 5%, a sample size of 139 would be needed to detect superiority between Allen Carr, and the service delivered by Quit.ie.

Primary Endpoints:

- Quit rates at 3 Months

Secondary Endpoints:

- Quit rates at 1 Month
- Quit rates at 6 months
- Quit rates at 12 Months
- Weight gain
- Reduction in Cigarette Consumption

Ethics:

Ethical approval will be sought from DIT Ethics Committee prior to beginning of the project. All documentation relating to the project will be provided for ethical review. There are no perceived Ethical issues as patients will be fully informed of all treatments on offer. Varenicline and NRT may be prescribed to some of the participants in the quit.ie arm of the study. Varenicline is prescribed for a 12 week treatment period and is an FDA/IMB approved prescription medication for smoking cessation. It binds to the same brain receptors as nicotine from tobacco. Varenicline has been shown to increase the odds of successful quitting two to threefold relative to placebo with an estimated 6 month abstinence rate of approximately 28% compared with 12% for placebo pills(6). NRT can be prescribed in many forms such as patches, gum, lozenges, inhalers and nasal sprays all of differing strengths. NRTs increase the rate of quitting by 50 to 70%, regardless of setting (7). These treatments are usually for a 3 month period and a combination of delivery methods and strengths can be used.

All participants will be provided with a patient information leaflet and asked to sign an informed consent form. (Appendix 1)

Methodology

Recruitment

The sample will be recruited through public advertisement on which it will state that all those that complete the program will be entered into a draw for 1st Prize a 2 week Caribbean holiday for two, 2nd prize a weekend for two in Paris, 3rd prize an iPad.. The potential

subjects will be screened by TFRI to determine their eligibility for inclusion in the study. Those who meet the criteria and are willing to participate (Appendix 2) will be allocated randomly to

- 1) The Allen Carr programme
- 2) Quit.ie services

The AC Easyway treatment will be delivered by AC Easyway Ireland. The Quit.ie services will be delivered either online, by phone, in groups or on a one to one basis as per the clients' requirements. All participants who complete the program will be entered into a 3 prize draw for 2 week holiday, a weekend holiday and an iPad.

Consent:

Once eligibility has been determined patients will be given an appointment where they will receive an information leaflet. Once this has been read and any concerns of the participant addressed and explained, they will then be asked to provide written consent prior to their randomisation and study enrolment. Consent will be obtained from all participants prior to randomisation. Consent is on-going and participants can revoke consent at any stage of the project. (Appendix 1)

Randomisation:

Randomisation will be carried out by telephone. Each consented patient will be randomly allocated to one of the two study arms. The randomisation will be made by submitting details of the consenting patient:

- Gender
- Age
- Socioeconomic group defined by highest education level reached: Primary
Secondary, Third level
- Readiness to Quit scale questionnaire. (Appendix 2.)

Once this has been processed they will be then allocated to one of the treatment arms and given a unique Patient identifier code, this will try and ensure that there will be an equal number from each category in each treatment arm and that the patient data can be stored and handled in a de-identifiable manner.

Patient randomisation will be performed by TFRI; participants will be randomly assigned to either:

Arm 1: Allen Carr's Easy way to stop smoking.

Participants will complete a one day delivery of the Allen Carr's Easy Way to stop smoking seminar. Their quit status will be tested at month 1, month 3, month 6, and month 12 following treatment. The essentials of the method are included in (Appendix 3).

Arm 2: Quit.ie service.

Information regarding details of the quit.ie service will be given to the patient and the method in which they will enrol with the service will be established (online, phone or in person). It will be agreed that they will be contacted by phone within two weeks of randomisation to confirm their registration in the programme. Their target quit date will be confirmed and an appointment for validation of their quit status will be made at month 1, month 3, month 6 and month 12 following their target quit date (TQD). (Appendix 4)

Follow up visits:

Validation of quit status will be carried out in a clinical setting using a CO monitor. The breath CO monitor can indicate whether an individual is 'smoke free'. This is the validation method of choice for smoking cessation services due to its low cost, ease of use and instant results. The monitor to be used in this study is the Care fusion CO monitor.

To test for smoke-free in a patient, they are instructed to take in a deep breath, hold it for at approximately 20 seconds and then exhale slowly and completely into the CO monitor. The monitor displays parts per million (PPM) of Carbon Monoxide on its clear LCD display, and when used in conjunction with the smoking cessation guide chart, %COHB are readily available.

The CO Monitor features single-button operation and coloured light indicators to simplify patient understanding of the process:

- Green: 0 to 6ppm

- Amber: 7 to 10ppm
- Red: 11 to 20ppm
- Flashing red and alarm: >20ppm

Other support for the Project

Advisory Panel

The trial will be advised by an international panel including Prof Linda Bauld, who has expressed an interest, Prof Dr. A. Dijkstra, University of Groningen who has Allen Carr experience and Prof Michael Barry, National Centre for Pharmacoeconomics, NCPE Ireland who has already offered advice.

Safety Considerations

The safety of all research participants will be considered at all times, they will be seen in an insured medical practice on 5 occasions over their 12 month participation.

The RCT will be registered at <https://www.clinicaltrialsregister.eu/>

Data Management and Statistical Analysis

All data will be stored on a secure server and will be de identified. Data will be entered giving each participant a unique identifier code, neither their name, address or date of birth will be recorded in order to protect the confidentiality of the participant. Analysis will be carried out on a blinded dataset using SPSS.

An allocation of 1:1 was selected. With 80% power and two-sided significant level of 5%, a sample size of 139 in each Arm would be needed to detect superiority between Allen Carr, and the service delivered by Quit.ie.

Quality Assurance

Data will be entered at source and will be verified by both the treating physician and clinical nurse specialist. The data will be further examined by Dr Kate Babineau and any anomalies found will be addressed and resolved from source data.

Expected Outcomes of the Study

A report of the project will be produced for the funding agency and the participant organisations.

A scientific paper will be prepared and submitted for peer review in an appropriate international scientific journal.

Recommendations as to the role of both methods used will be made to the relevant bodies who supply or commission smoking cessation services.

Dissemination of Results and Publication Policy

TFRI will prepare the relevant reports and papers and make recommendations based on the outcomes achieved. The results will be propagated through different channels. For instance, summaries can be posted in more than one webpage (TFRI, Dublin Institute of Technology (DIT), the Health Service Executive (HSE), Asthma Society of Ireland and relevant NGOs e.g. ICS, IHF, ASH Ireland), including more European centred venues such as the European Network for Smoking Prevention (ENSP). These websites will reach different audiences and it is likely that the focus of each summary or paper will be individually tailored. Collaboration with ASH Ireland advocacy group will bolster dissemination for the current study.

Findings from the study will be submitted for publication in peer-reviewed journals in the corresponding disciplines (environmental and respiratory health, clinical and Tobacco Control journals). In addition, poster and/or oral presentations of the results will be presented at scientific, policy and advocacy meetings in Ireland and internationally.

Problems Anticipated

Difficulties are predicted in the recruitment of adequate number of participants. It is envisaged that we will have a strong advertising campaign on line on social media sites such as Twitter, Facebook, and quit.ie; in print in the form of newspaper advertising; and in Healthcare settings such as Primary Care Centres, Dental practices and GP surgeries. The advertising will be stepped up if recruitment is not meeting the required number of participants. Attrition will also be a problem and in that regard it is proposed:

- To issue a follow up appointment.
- On failure to attend this, participants will be followed up with a phone call and a second appointment offered.
- Upon failing to attend a second appointment a final phone contact will be made from which self-reported data will be gathered.

Project Management

Luke Clancy is the project supervisor.

Sheila Keogan will be responsible for the management of the project, obtaining consent of all participants in the project, randomisation to both treatment arms and validation of quit status of all participants in both treatment arms of the project.

Kate Babineau will be responsible for issuing of the patient randomisation and will aid in verifying validity of data and the statistical analysis.

Curriculum Vitae of investigators Appendix 5

CV of Professor Luke Clancy

CV of Ms Sheila Keogan

CV of Dr Kate Babineau

Duration of the Project

The project is to run for a 3 year period starting September 2014 and completion is expected by October 2017.

Gantt chart

	Months											
	1 - 3	4 - 6	7 - 9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36
Planning Meetings with Collaborators												
Project Design												
Ethics submission												
Advertising Plan												
Advertising												
Recruitment												
Follow up and Final evaluation												
Annalysis of results												
Report Writing												
Dissemination of results												

Appendix 1. Patient Information Sheet and consent form

Part I: Information about the research project and the interview process

Is Allen Carr's Easyway to Stop Smoking Programme superior to Smoking Cessation service delivered by Quit.ie? a randomised controlled trial

What is this study about?

This project is a randomised controlled trial which will test the 12 month smoking cessation success rate of the Allen Carr Easyway against standardized smoking cessation service delivered by quit.ie.

What does participation involve?

After determining your eligibility, establishing your willingness to take part, and receiving your active consent, a researcher will arrange an appointment where you will be randomised to one of three conditions:

1. **Allen Carr Easyway to Stop Smoking:** An appointment will be made for you to participate in a full day, AC Easyway treatment programme. Follow up appointments will be required at 1, 3, 6, and 12 month intervals in order to verify your smoking status. TFRI staff members will contact you to arrange these appointments. Your attendance is expected and you will be reimbursed for any travel costs incurred.
2. **Quit.ie service:** You will receive information on how to access and best utilise the Quit.ie service. If assigned to this group, you will be reviewed at 1, 3, 6, and 12 month intervals following the treatment to verify your smoking status at these time points. TFRI staff members will contact you to arrange these appointments. Your attendance is expected and you will be reimbursed for any travel costs incurred.

How do you decide which group I get assigned to?

Your group allocation will be done completely at random based on a series of demographic questions. We want to make sure that we have equal groups based on age,

gender, and smoking habits. We do not base our grouping on any other factors and we cannot honour any individual requests for grouping. Once you are assigned a group, you cannot be reassigned.

Do I have to participate?

Absolutely not, participation is 100% voluntary. No one will be included in any stage of the research unless they have given consent. Participants can revoke consent at any stage of the process.

Will this be confidential?

All information that is gathered in this study remains 100% confidential. Your information will be stored in a de-identified form on a secure computer that is only used by members of the research team. No one will have access to the information gathered in this study aside from the researchers and it will only be used for research purposes. There will be no identifiable information stored in the computer at any stage during this research.

Who is running this study?

Department of Health Lottery fund is funding this study with The TobaccoFree Research Institute (TRI) who is carrying out this research. Allen Carr Easy way to stop smoking is funding their treatment provided for this study. TFRI was formed on the basis of a partnership between the Office of Tobacco Control and ASH Ireland. The Institute supports the development of a tobacco free society by engaging in research in all aspects of tobacco from a public health perspective to provide the evidence base for action.

It is only by conducting studies such as these that we are able to understand and validate alternative methods for use as a smoking cessation treatment. Through studies like this, we are able to work towards promoting the health of smokers in Ireland and abroad.

We hope that you can support us in our work and we would like to thank you, in anticipation, for your help.

Participant Consent

Is Allen Carr's Easyway to Stop Smoking Programme superior to Smoking Cessation service delivered by Quit.ie? a randomised controlled trial

I have read the information sheet pertaining to the project

I understand that research is being conducted by The TobaccoFree Research Institute Ireland and that my participation is completely voluntary.

I understand that my allocation to a group is completely random

I understand that by agreeing to take part in the study that it will involve me attending multiple scheduled visits to the research centre over the period of one year. All visits are required in order to be involved in the study.

Participant Name (Print) _____

Participant Signature: _____,

Date; _____,

Investigator Name: (Print) _____,

Investigator Signature: _____,

Date: _____

Appendix 2. Readiness to Quit Questionnaire & Randomisation.



Unique Identifier code:

Eligibility screening:

Inclusion criteria:	Yes	No
How many cigarettes do you smoke per day?		
Are you over 18yrs?		
Are you willing to attend all study visits? They will all be conducted in Dublin (4-5 visits over 12 month period)		
Are you willing to give written informed consent?		
Do you have a good knowledge of English?		

If **NO** to any of the above subject must be excluded from the study

Exclusion criteria:	Yes	No
Are you undergoing treatment for alcohol or illicit drug abuse?		
Has a Doctor diagnosed you with acute cardiac or respiratory conditions?		
Has a Doctor diagnosed you with a serious psychiatric illness?		

If **YES** to any of the above subject must be excluded from the study

Randomisation:

1. Are you Male Female

2. What is your age?

3. What is the highest level of education you have achieved?

Primary School Junior Certificate Leaving certificate College Degree



Please answer the questions below:

	Yes	No
Are you a smoker who is interested in quitting in the next month?		
Are you willing to set a quit date		
If yes to above questions would you like to enrol in the project ' <i>Is Allen Carr's Easyway to Stop Smoking Programme superior to Smoking Cessation service delivered by Quit.ie? A randomised controlled trial</i>		
<p>How Ready Are You?(circle the appropriate number) Sliding scale 1 = not at all 10 = Completely</p> <p>How important is it for you to Quit Smoking for good? 1 2 3 4 5 6 7 8 9 10</p> <p>How practical is it for you to Quit Now? 1 2 3 4 5 6 7 8 9 10</p> <p>How confident are you to do what it takes to quit smoking For Good? 1 2 3 4 5 6 7 8 9 10</p>		

Readiness to quit Assessment: _____

Signed: _____

Date: _____

Appendix 3 Allen Carr Easy way to stop smoking.

(<http://allencarr.com/42/how-the-clinics-work>)

Allen Carr Easy way to stop smoking: A cognitive stop smoking method. Stop smoking therapists are expert in the Allen Carr's Easyway method. They have all used the method to quit smoking themselves and undertook our rigorous selection and training process to become qualified and practising Members of the Association of Allen Carr Therapists International (MAACTI). You will find them understanding and sympathetic about any concerns you may have about stopping smoking. The stop smoking clinic sessions take approximately 4-6 hours and are held in groups of up to 20 people. Most people need just one session, but shorter booster sessions are available, free of charge, for the few people that require them. A fully trained Allen Carr's Easyway therapist conducts the sessions. Smokers are encouraged to take regular smoking breaks throughout the session, and the session climaxes as the group smoke a final cigarette and throw their cigarettes and lighters on a pile at the front of the room. The therapist focuses on the reasons why we smoke rather than why we shouldn't. Smokers already know that it is unhealthy, costly and sometimes an anti-social thing to do. The session, using a combination of psychotherapy and hypnotherapy, removes the smoker's belief that smoking provides any sort of genuine pleasure or crutch. It removes the feeling of sacrifice and deprivation and therefore rids the smoker of the fear of stopping. Most smokers mistakenly fear that they will be unable to enjoy life or cope with stress without cigarettes when they quit.

The Allen Carr's Easyway Method removes this fear.

By removing the need and desire to smoke, the need for willpower is also removed. The method channels the smoker's will against the cigarette rather than leaving them to struggle with a conflict of wills. Clients are happy to become non-smokers from the moment they stub out their last cigarette. They are confident that they can enjoy social occasions more and handle stress better when they stop and, more importantly, they realise that they need not miss smoking. Most of the clients attending Allen Carr's Easyway Clinics do so, on the strength of the personal recommendation of friends, colleagues and members of their family who quit by using Allen Carr's Easyway Method.

Why Attend an Allen Carr's Easyway Clinic?

Millions of people have successfully stopped smoking by using Allen Carr's Easyway Clinics and books. The clinics continue to be the most powerful and effective way of receiving Allen Carr's Easyway method – hence our ability and willingness to offer our

money-back guarantee.

The advantages of attending a clinic –

There is a money back guarantee. The clinic sessions are effective whether you have read the book or not. Even if you failed to stop by using the book, the clinics will work for you. In fact, we will discount the cost of any Allen Carr's Easyway book if you bring it along to your session! You can ask questions as they come to mind. And you'll get a real, live, straight answer from someone who has themselves used Allen Carr's Easyway method and has received comprehensive training to become a Senior Allen Carr's Easyway therapist. You'll be shown a strategy to help you break through your fears and easily deal with anything that may previously have led to temptation. This is done using powerful psychology aimed at the conscious mind, reinforced at the end of the session by hypnotherapy. You get to share your experience (if you wish) and those of other participants, often realising you are not the only one with your particular fears and worries. Although you will be given everything you need in one session to become a happy non-smoker for life, if you should need support after you leave us, free back-up sessions and telephone support is available. You can book into your nearest clinic online or by telephone or just call for an informal no-obligation chat.

Success Rate

“The success rate at Allen Carr's Easyway Clinics is over 90% based on the three month money-back guarantee and independent scientific studies indicate that, even after 12 months, the success rate remains over 51%*"

This is unprecedented in the field of smoking cessation

*Long-term success of short smoking-cessation seminars supported by occupational health care', H. Moshammer, M. Neuberger. Addictive Behaviours (2007) Success Rate 51.4% after 3 years and 'Smoking cessation at the workplace: 1 year success of short seminars,' H.P Hutter, H. Moshammer, M.Neuberger. Internal Archives of Occupational Environmental Health (2005) 40% (worse case) 55% (best estimate).

Comparing Allen Carr's Easyway with other methods:

Believe it or not, there is no resource for smokers to compare the success rates of various quit smoking methods. Given the amount of money that has been spent in this area of research, we find this odd. The reason for this is that researchers do not compare methods head-to-head; they typically compare them to placebo, or to no treatment. This enables manufacturers of Nicotine Replacement Therapy products, for example, to make claims such as NRT “doubles your chances” of quitting. However we believe that smokers are

much more interested in the question: “Double them from what to what?” Allen Carr’s Easyway are currently considering the commissioning of a randomized, controlled trial at a cost of approximately £800,000. This trial would compare Allen Carr’s Easyway Clinics to the NHS Stop Smoking Service in the UK. We have more than 150 centres in more than 45 countries worldwide, all of which offer the same money-back guarantee. You have nothing to lose and everything to gain.

Our Money Back Guarantee

Allen Carr founded his stop smoking method in 1983. Since then his organisation has spread throughout the world curing smokers in more than 58 countries and 38 languages. Allen Carr became widely regarded as the leading expert in his field and the reputation of Allen Carr’s Easyway to Stop Smoking has grown for the simple reason that the method works. As far as we are aware, ours is the only established organisation which actually offers a money back guarantee if you do not succeed in stopping. We are able to offer this guarantee because our success rate is so high – over 90% based on the 3 month money back guarantee. If you genuinely want to stop smoking, our method will not only enable you to do so but will also make it relatively easy. If you follow the instructions you will not only become a non-smoker but you will find the withdrawal period completely painless and most important of all you will not miss smoking. Most smokers require just one session to become happy non-smokers. In certain cases, however, more than one session is required. In this event there is no extra charge, the initial fee covers all sessions.

TERMS OF THE GUARANTEE

If within three months from the date of your first session you are still smoking and decide not to stop, your fee will be refunded in full without inquisition. Your word will be taken on trust. However, we would request you on your part to be genuine in your desire to stop. This guarantee will be invalidated in any of the following events:

- (1) That you cancel, postpone or fail to attend any session or arrive over fifteen minutes late for any session.
- (2) That you fail to attend at least two free back-up sessions within three months of the date of your first session (the second and third sessions are not a repeat of the first session and last approximately 2½ – 3½ hours each) Should you stop smoking for three months or longer but start again at a later date, you may attend any number of back-up sessions on payment of half the standard fee. However, once you have not attended a full first session in the preceding 12 months you would need to attend the first session again, the standard fee will be payable and the guarantee will apply.

Appendix 4: Quit.ie Service.

The QUIT team on Quit.ie now provide support to quitters across a range of channels – over the phone, on Twitter and Facebook, and by SMS and email. Quitters can also use the brand new interactive QUIT.ie website, talking to the QUIT team via Live Chat, and using our online QUIT plan. As well as the new online and phone based support there is a network of face-to face HSE QUIT services in many locations around the country, providing one-to-one and group support for smokers.

However a smoker chooses to access our service, the QUIT team offers evidence-based care through a standard treatment programme, where quitters will be tracked and supported for 12 months to help them quit and stay quit. Our trained advisors will provide quitters with support, advice and the evidence-based quit programme, over the phone, via Twitter and Facebook, or by email and SMS.

- Quitters are offered a 20 minute phone consultation, which can be scheduled for any convenient time, where their own smoking habits, triggers and reasons to QUIT are analysed. If the smoker is ready to Quit they set the date. The quit team schedule calls for the Quit date and once a week for the first 4 weeks. There are follow up calls at 3 months and 12 months Quitters can call, text or use Facebook to contact the Quit will usually speak to the same advisor throughout the process.
- The QUIT.ie website has been completely redesigned and updated to match the new QUIT support service. The site is mobile and tablet friendly, and for users who prefer to QUIT without one-to-one support, offers an independent QUIT plan, with daily email and SMS support, and an option to Live Chat with an advisor if needed. Quitters can log in at any time to check on their progress, how much money they've saved, how far they've come and find answers to common questions.
- The QUIT team are also contactable on Twitter@hseQuitTeam and on the YoucanQUIT Facebook page, which is now approaching 100,000 likes and has become a daily hub for current and former quitters, helping and supporting each other along the way. For 2015, the new QUIT Heroes app on our Facebook page encourages people to share their quit story and what worked for them, in order to help other quitters toward success and every month there will be a small reward to the QUIT Heroes who provide the greatest support to fellow Quitters.

- Quitters can also order a QUIT kit on quit.ie which includes the QUIT booklet guide to quitting, a money box for saving the cash not spent on cigarettes, a wristband and pencil, a wallet card and post-it pack
- All QUIT services are provided free of charge by the HSE

Appendix 5: Curriculum Vitae

Professor Luke Clancy

Address 45 Park Avenue, Sandymount, Dublin 4 Home

Telephone Mobile: + 868364337

E-mail lclancy@tri.ie

Nationality Irish

Gender Male

Work experience

Dates 2003 to Date

Director General TFRI / Visiting Professor Dublin Institute of Technology

Responsible for the scientific and executive management of the TobaccoFree Research Institute, which carries out and promotes research to the highest academic standards into all aspects of tobacco.

TobaccoFree Research Institute, DIT, Focas Research Institute, Camden Row, Dublin 8.

Dates 2006 – to date

Consultant Respiratory Physician

Provision of a high standard of medical care to respiratory patients

Dates 2000 - 2006

Professor Respiratory Medicine

Lecturing to clinicians in all aspects of respiratory medicine. Supervision of post graduate students.

Trinity College, Dublin 2, Ireland.

Dates 1978 -2005

Consultant Physician Respiratory Diseases/ Clinical Director

Leading a clinical team in providing a high standard of medical care to respiratory and general medical patients. Teaching and training junior staff and undertaking clinical audit and relevant research. As clinical director (1993-2003) having managerial responsibility for the Cardiothoracic Directorate.

St. James's Hosp. James's Street, Dublin 8, Ireland.

Dates 1981-2004 (part – time)

Medical Director

Clinician and Managerial

Peamount Chest Hospital, Newcastle, Co. Dublin

Dates 1988 -1999 (part – time)

Senior Lecturer in Respiratory Medicine

Trinity College, Dublin 2, Ireland. Third level education provider.

Dates 1976-1978

Consultant Physician in Respiratory Medicine

Main activities and responsibilities: Leading a clinical team in providing a high standard of medical care to respiratory and general medical patients. Teaching and training junior staff and undertaking clinical audit and relevant research.

Nottingham Area Health Authority, Nottingham, England.

Education and training:

Dates 2009

PhD, Air pollution and second hand smoke, Dublin Institute of Technology

Dates 1996

Fellow of the Faculty of Occupational Medicine Royal College of Physicians Ireland (F.F.O.M.R.C.P. (Ire))

Dates 1995

MD (General Internal Medicine) National University of Ireland

Dates 1984

Fellow of the Royal College of Physicians Ireland (F.R.C.P. (Ire))

General Internal Medicine, Royal College of Physicians Ireland

Dates 1981

Fellow of the Royal College of Physicians Edinburgh (F.R.C.P. (Edin)), General Internal Medicine

Dates 1976

Joint Committee Higher Medical Training, Royal College of Physicians – Accreditation

General Internal Medicine and Respiratory Diseases. Royal College of Physicians UK

Dates 1972

Member of the Royal College of Physicians UK (F.R.C.P. UK), General Internal Medicine

Name and type of organisation providing education and training Royal College of Physicians UK

Dates 1966

M.B., B.Ch, B.A.O, General Internal Medicine, National University of Ireland

Hons, Degree, 1st place ex. Aqueo, Awarded Gold Medal.

Dates 1963

BSc, (Physiology) Respiratory Physiology, National University of Ireland

Hons. Degree, N.U.I., 1st place ex. Aqueo.

Social skills and competences

Strong Leadership skills and Experience.

Participates well as part of a team.

Excellent communication and presentation skills

Advocacy skills. Confident negotiator.

Ability to network effectively at all levels.

Adept in coalition building and establishing collaborative relationships.

Works well with men and women and with a variety of ethnic, social, or educational backgrounds.

Organisational skills and competences:

Proven ability to lead and motivate a multidisciplinary team.

Sensitive to diversity and multiculturalism

Able to manage human, material and financial resources effectively.

Ability to manage conflict and resolve difference.

Ability to project manage effectively and to work to tight deadlines.

Manages information effectively.

Technical skills and competences

Competent medical practitioner with specialist expertise in respiratory medicine.
Highly developed research skills including research project design, proposal writing, data collection and analysis, interpretation of research findings, writing of research reports and presentation of research results. Ability to supervise post graduate research students, teaching skills.

Computer skills and competences:

Proficient in Word, Excel, PowerPoint, Internet and Email.

Understands database operations and management information systems.

Artistic skills and competences Strong interest in music and film.

Other skills and competences Ability to attract research funding.

Understanding of social policy issues.

Ability to analyse political support and opposition.

Understanding of economic issues.

Dr Kate Babineau

Kate Babineau

+353 86 078 1060 /

kate.babineau@gmail.com

Education

PhD, Child and Youth Research, Trinity College Dublin

2013

Thesis Title: *Designing a Child-Centered Quantitative Measure of Inter-ethnic Relations: A Mixed Methods Study*

MSc, Applied Social Research, Trinity College Dublin

2009

Thesis Title: *Encountering Children in Distress: The Role of Social Researchers*

B.A., Philosophy and Political Science, Loyola University New Orleans

2006

Research Experience

TOBACCOFREE RESEARCH INSTITUTE

Dublin, Ireland

Postdoctoral Researcher

Jan 2014 - Present

- Develop, design, conduct, analyse, and present various research projects on tobacco use among youth and adult populations.

COOLMINE THERAPUTIC COMMUNITY

Dublin, Ireland

Researcher: Pathways through Treatment Study

Jan 2011 - Present

- Conduct on-going qualitative interviews, track participants, analyse data, and write final report of a longitudinal mixed-methods study of drug treatment service users.

TRINITY IMMIGRATION INITIATIVE

Dublin, Ireland

Research Assistant: Be Fair: Say No to Racism Project Aug 2012 – Aug 2013

Children, Migration, Diversity Project Mar 2008 – Aug 2008

- Coordinated school recruitment, conducted interviews with teachers, and composed research reports contributing to the development of an anti-racism program for primary school children.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Cambridge, MA

Research Assistant: Department of Anthropology Sept 2005 – Jan 2006

- Coded and analyzed qualitative data on an ethnographic study of the development and implementation of a new environmental, health, and safety system in MIT laboratories.

Teaching Experience

TRINITY COLLEGE, SCHOOL OF SOCIAL WORK AND SOCIAL POLICY

Dublin, Ireland

Teaching Assistant

Masters in Applied Social Research: Qualitative Module Aug 2011 –

Present

Introduction to Social Policy Aug 2010 – May 2011

Additional Experience

UNITED WAY OF TUCSON AND SOUTHERN ARIZONA

Tucson, Arizona

Youth Development Project Manager Dec 2008 – Oct 2009

- Directed the implementation and evaluation of a federally funded physical education curriculum in afterschool programs, designed evaluation tools, managed program budget, researched and secured additional grant funds for program expansion.

AUDUBON CHARTER SCHOOL

New Orleans, LA

Assistant Teacher, After School Program Coordinator

Aug 2006 –

Aug 2007

- Planned and taught daily lessons for 4th and 5th class students, contributed to the development and implementation of an after-school program for children ranging in age from 3 to 12.

Conferences

Babineau, K., Clancy, L., Keogan, S. (2015). *Perceptions of Plain Packaging: A cross-sectional study of Irish teenagers*. Accepted for the World Conference on Tobacco and Health. Abu Dhabi, UAE.

Babineau, K., Clancy, L., Keogan, S. (2015). *E-Cigarette Use among Irish Teenagers: A cross-sectional study*. Accepted for the World Conference on Tobacco and Health. Abu Dhabi, UAE.

Babineau, K. (2014). *Child-centered Cognitive Interviews*. Presented at the European Congress of Methodology. Utrecht, NL.

Babineau, K. (2014). *Child Centerdness: In Theory and In Practice*. Presented at the Sociological Association of Ireland Postgraduate Conference. Galway, Ireland.

Babineau, K. (2012). *Challenges of Designing a 'Child-Centered' Quantitative Measure*. Presented at Children and Youth Research Symposium. Galway, Ireland.

Honors & Awards

2012-2013: Trinity College School of Social Work and Social Policy PhD Studentship.

2009-2012: Trinity Immigration Initiative PhD Studentship with the Children, Youth, and Community Relations Project, Trinity College Dublin.

2006: Political Science Student of the Year, Loyola University, New Orleans.

Ms Sheila Keogan

Address: 43 Glenbrook Park
Rathfarnham,
Dublin 14

Phone: Mobile/work 087 6887678
Home 01 4935031

Email: skeogan@tri.ie
shekeogan@gmail.com

Registered with An Board Altranais No 19203.

Current Employments

Research and Communications

Research Institute for Tobacco Free Society (RIFTFS)
The Digital Depot,
Thomas Street,
Dublin 8
Re-instated in September 2014

2004 – to date
24 hrs per week

Respiratory Nurse Manager (CNM11)

St James's Hospital
Respiratory Clinics

1986 – to date
14.25hrs per week

Smoking cessation weekly outpatient clinic St James's Hospital 2011 to 2013

Previous posts held

Cardiology Research co-ordinator

St James's Hospital,
James's Street,
Dublin 8

2014 for 8 months
24hrs

Respiratory Research Nurse/Asthma Nurse/

Clinical trials co-ordinator
St James's Hospital

1986 – 2004

Staff Nurse in Care of the Elderly/General Medicine

Dr. Steevens Hospital

1985 – 1986

Staff Nurse in Plastic and General Surgery

Dr. Steevens Hospital

1985

Theatre Staff Nurse

Dr. Steevens Hospital

1983 - 1985

Accounts Clerk

Lee & Co wholesale Cash & Carry
Belgard Road,

1979 - 1980

Cookstown Industrial Estate,
Tallaght,
Dublin 24

Au Pair/ Studying French 1978-1979
Brussels/ Leuven, Belgium

Professional Qualifications:

Masters of Philosophy (MPhil) 2012
'Evaluation of Smoking Cessation Services in Ireland:
Design and pilot of a smoking cessation treatment database'

General Nurse Training (RGN) 1980 – 1983
Dr. Steevens Hospital,
Steevens Lane,
Dublin 8

Professional Development:

Practical Course in Health Research Methods 2014
Royal College of Surgeons in Ireland

Smoking Cessation Training Update 2011
Ulster Cancer Society

Advanced Smoking Cessation Course London 2008
Smoking Cessation Training and Research Programme (SCTRP)

Good clinical practice course 2001/2014

Smoking Cessation Course. Irish Cancer Society 1997

Asthma Specialist Training. 1990/1992
Stratford upon Avon
UK

IT Training

MS Project Management course 2005
ECDL 2004

Skills & Experience

Clinical:

Patient advice and education in all respiratory diseases, which involves:

- Asthma and COPD Management.
- Out Patient Clinic Management
- Providing support and care for patients with respiratory conditions and those wishing to stop

- smoking.
- Spirometry/ Histamine Challenge/ skin testing.
- Smoking cessation service.
- Lung cancer patient care co-ordinator and monitoring of results.
- Development and management of clinical databases.

Theatre experience Included 18 months of:

- General surgery.
- Orthopaedic surgery.
- Plastic and micro surgery.

General Nursing as a staff nurse included:

- Care of the elderly
- General & Plastic surgery
- Orthopaedics and Burns

Research:

Clinical Research:

Multicentre and single centre clinical trials in the treatments of lung cancer, asthma, COPD, community acquired pneumonia, cardiology and smoking cessation. This involved:

- Recruitment of patients.
- Conducting all necessary tests and coordination with various laboratories.
- Keeping accurate records, subject to both internal and external audits.
- Ethical approval applications.
- Finance negotiating.

Academic research:

- RCT project design and protocol development
- Project Management of an FP7 project and management of development of www.ppacte.eu
- Collaboration with DIT, UCD, UCC, St James's Hospital, the Asthma society, the INMO, IMO, and the IDA on various research projects and also supervision of students during work placement and research projects leading to master degrees.
- Preparation of research grant applications.
- Input into research proposals and design.
- Poster/Abstracts/Oral presentation of research results, nationally and internationally (Publication list attached).
- Analysis of results using SPSS
- Data Management.
- Preparation of press releases and dealing with press enquiries.

Management:

Project management.
Event Management.
Public Relations.
Office Management.
Annual Reports.
Company accounts
Board and Committee management

IT:

Data Management
Database development
Management of IT function for TFRI
Website design & Management
SAGE accounts software
SPSS Statistical software
All MS office applications

Hobbies Interests

Photography, art, music, travel and all that is gadget and IT related.

Publications

Smoking and Tobacco Control Survey of Healthcare Professionals (HCP) in Ireland

S. Keogan, V Clarke, A. Burns, L Clancy
IRJ Med Science Nov 2013.

Tobacco Free Playground -Millennium Park, Dublin 15 Initiative

V. Clarke, C, Hayden, M. Gunning, C. Wilde, M. Ward, K. Halpenny, S. Keogan, L. Clancy.
IRJ Med Science Nov 2013.

How high is the level of illicit Tobacco trade in Ireland?

L Clancy, L Currie, S Keogan, V Clarke.
For PPACTE Consortium, IRJ Med Science Nov 2013

Findings on Pregnant smokers attending smoking cessation services in Ireland

S. Keogan, Z Kabir, V Clarke, P Goodman, L Clancy
European Respiratory Society, Sept 2013

Maternal Smoking Rates and associated adverse birth outcomes in an Irish Hospital over the ten year period 2000 – 2009.

V. Clarke¹, Z. Kabir¹, S. Keogan¹, L Clancy¹
European Respiratory Society, Sept 2013

Smoking ban and small-for-gestational age births in Ireland.

PLoS One. 2013;8(3):e57441. doi: 10.1371/journal.pone.0057441. Epub 2013 Mar 26. Kabir Z, Daly S, Clarke V, Keogan S, Clancy L.

Evaluation of Smoking Cessation Services in Ireland: Design and pilot of a smoking cessation treatment database. Sheila Keogan.

MPhil Thesis DIT 2012

Findings on Pregnant smokers attending smoking cessation services in Ireland

S. Keogan, Z Kabir, V Clarke, P Goodman, L Clancy
Ir J Med Science 2012

Maternal Smoking Rates and associated adverse birth outcomes in an Irish Hospital over the ten year period 2000 – 2009.

V. Clarke, Z. Kabir, S. Keogan, L Clancy
Ir J Med Science 2012

Prevalence & Predictors of Smoking cessation rates in Ireland: a follow-up cross sectional study

Ir J Med Science 2010 Vol 179 Supp. 12S495 10.8. S. Keogan, Z. Kabir, L. Currie. M. Gunning, P. Campbell, L. Clancy

Smoking profile among the Gay and Lesbian Community in Ireland

Ir J Med Sci. 2009 Jul 18. Kabir Z, Keogan S, Clarke V, Currie LM, Clancy L

Smoking Cessation Services in Ireland: Patient's satisfaction questionnaire survey

Ir J Med Science 2009 Vol Supp. S. Keogan, L. Currie, Z. Kabir, V. Clarke, L. Clancy

An evaluation of the range and availability of intensive smoking-cessation services in Ireland

Ir J Med Sci DOI 10.1007/s11845-009-0356-y

L. Currie, S. Keogan, P. Campbell, M. Gunning, Z. Kabir, L. Clancy

Second hand smoke exposure in cars and respiratory health effects in children

ERJ Express. Published on April 8, 2009 as doi: 10.1183/09031936.00167608 Zubair Kabir, Patrick J Manning, Jean Holohan, Sheila Keogan, Patrick G Goodman, Luke Clancy

Smoking characteristics of Polish immigrants in Dublin

BMC Public Health 2008, 8:428 (31 Dec 2008) Zubair Kabir, Vanessa Clarke, Sheila Keogan, Laura M Currie, Witold Zatonski and Luke Clancy

Prevalence of smoking in cars in Ireland: cross-sectional surveys

Irish Journal of Medical Science.

Vol 177. Supp 13. pg S446 Nov 2008 Kabir Z, Keogan S, *Manning PJ, *Holohan J, 1Goodman PG, Clancy L

Research Institute for a Tobacco Free Society, Dublin; *Asthma Society of Ireland, Dublin; 1 Dublin Institute of Technology

Smoking profile of the Gay and Lesbian Community in Ireland

Irish Journal of Medical Science.

Vol 177. Supp 13. pg S446 Nov 2008

Keogan S, Clancy L, Clarke V, Currie L, Kabir Z

Research Institute for a Tobacco Free Society, Dublin

The range and availability of smoking cessation services in Ireland

The International Journal of Tuberculosis and Lung Disease

Vol 12 No;11 2008 L. Currie; S. Keogan; P. Campbell; M. Gunning Z. Kabir; V. Clarke and L. Clancy

Prevalence and effects of active and passive smoking exposure on bronchitic symptoms in Irish school children

The International Journal of Tuberculosis and Lung Disease

Vol 12 No;11 2008 Luke Clancy, Patrick Manning, Jean Holohan, Sheila Keogan, Patrick Goodman, Zubair Kabir

Asthma and symptoms of wheeze, hay fever and bronchitis among Irish school children exposed to second-hand-smoke in cars

The International Journal of Tuberculosis and Lung Disease

Vol 12 No;11 2008 Zubair Kabir, Patrick Manning, Jean Holohan, Sheila Keogan, Patrick Goodman, Luke Clancy

Smoking characteristics of Polish immigrants in Dublin

European Respiratory Society

Vol 32 Supp 52 p3880 2008 Vanessa Clarke, Zubair Kabir, Sheila Keogan, Laura Currie, Witold Zatonski & Luke Clancy

Smoking and bronchitis symptoms among Irish school children: an ISAAC protocol study, 1995-2007

European Respiratory Society

Vol 32 Supp 52 (3154)2008 Luke Clancy, Patrick Manning, Jean Holohan, Sheila Keogan, Patrick Goodman, Zubair Kabir

Treatment of nocturnal asthma with nedocromil sodium.

Thorax. 1994 Dec;49(12):1225-7.

PMID: 7878557; UI: 95184105

Clancy L, Keogan S

References:

1. Currie LM, Keogan S, Campbell P, Gunning M, Kabir Z, Clancy L. An evaluation of the range and availability of intensive smoking cessation services in Ireland. *Ir J Med Sci.* 2010;179(1):77-83.
2. Killoran A, Jagroo J, Chatterton H, Ellis S. NICE public health guidance update. *J Public Health (Oxf).* 2013;35(3):475-6.
3. Coleman T, Chamberlain C, Davey MA, Cooper SE, Leonardi-Bee J. Pharmacological interventions for promoting smoking cessation during pregnancy. *The Cochrane database of systematic reviews.* 2012;9:Cd010078.
4. Hartmann-Boyce J, Stead LF, Cahill K, Lancaster T. Efficacy of interventions to combat tobacco addiction: Cochrane update of 2013 reviews. *Addiction.* 2014;109(9):1414-25.
5. Bullen C, Williman J, Howe C, Laugesen M, McRobbie H, Parag V, et al. Study protocol for a randomised controlled trial of electronic cigarettes versus nicotine patch for smoking cessation. *BMC Public Health.* 2013;13:210.
6. Cahill K, Stevens S, Lancaster T. Pharmacological treatments for smoking cessation. *Jama.* 2014;311(2):193-4.
7. Stead LF, Perera R, Bullen C, Mant D, Hartmann-Boyce J, Cahill K, et al. Nicotine replacement therapy for smoking cessation. *The Cochrane database of systematic reviews.* 2012;11:Cd000146.