UNIVERSITY OF CAMBRIDGE

Developing & Evaluating the Cambridge Breathlessness Intervention Service (BIS)

INSPIRED Workshop - Vancouver

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Breathlessness

- Common in advanced malignant and non-malignant conditions (e.g. COPD & heart failure)
- Difficult to treat and manage (pharmacological interventions frequently ineffective)
- Patients suffer: physical disability, loss of independence & dignity
- Families suffer: isolation, reduced activity, anxiety, role change

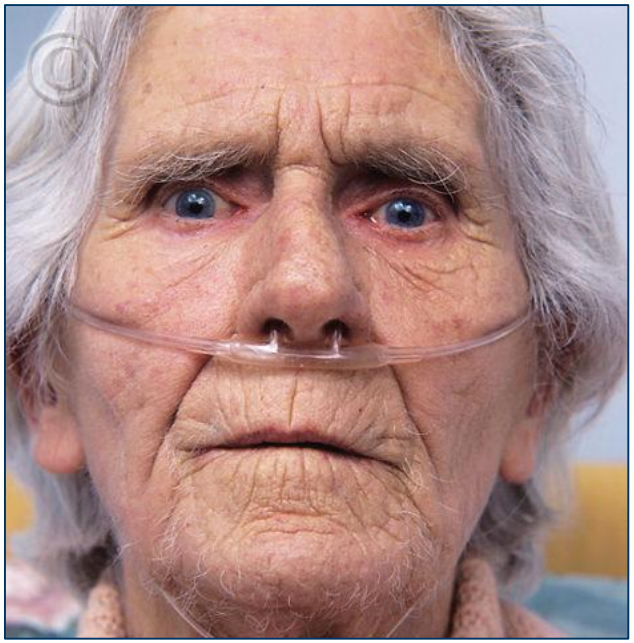
Breathlessness Intervention Service (BIS)

- Multi-disciplinary palliative care service: consultant, OT, physio
- Aims to help people live with breathlessness
- Any diagnosis (cancer or non-cancer)
- Works jointly with patients & carers, & advises referrers
- Hospital-based service - but functions in the community, in collaboration with primary care
- 'Toolkit' of pharmacological and non-pharmacological interventions

Booth S, Moffat C, Farquhar M, Higginson IJ, Bausewein C, Burkin J. Developing a breathlessness service for patients with palliative and supportive care needs, irrespective of diagnosis. *Journal of Palliative Care* 2011;27(1): 28-36.

Pharmacological

- Opioids (low dose oral morphine)
- Anxiolytics (benzodiazepines)
- Antidepressants
- Oxygen
- Nebulized drugs & saline
- Optimize dose & delivery
- Symptom management pain, nausea & vomiting, psychological distress



Non Pharmacological

- Reassurance, explanation & education
- Anxiety - cycle & management
- Handheld fan
- Activity & rehabilitation
- Breathing techniques
- Modifying ADL, pacing, good rest & positioning
- Airway clearance techniques
- Relaxation, visualisation, meditation
- Nutrition & hydration
- Personal / self management plan
- Positive psychological support, wellbeing interventions

Developing & Evaluating BIS

- New interventions require independent evaluation & feedback for effective development

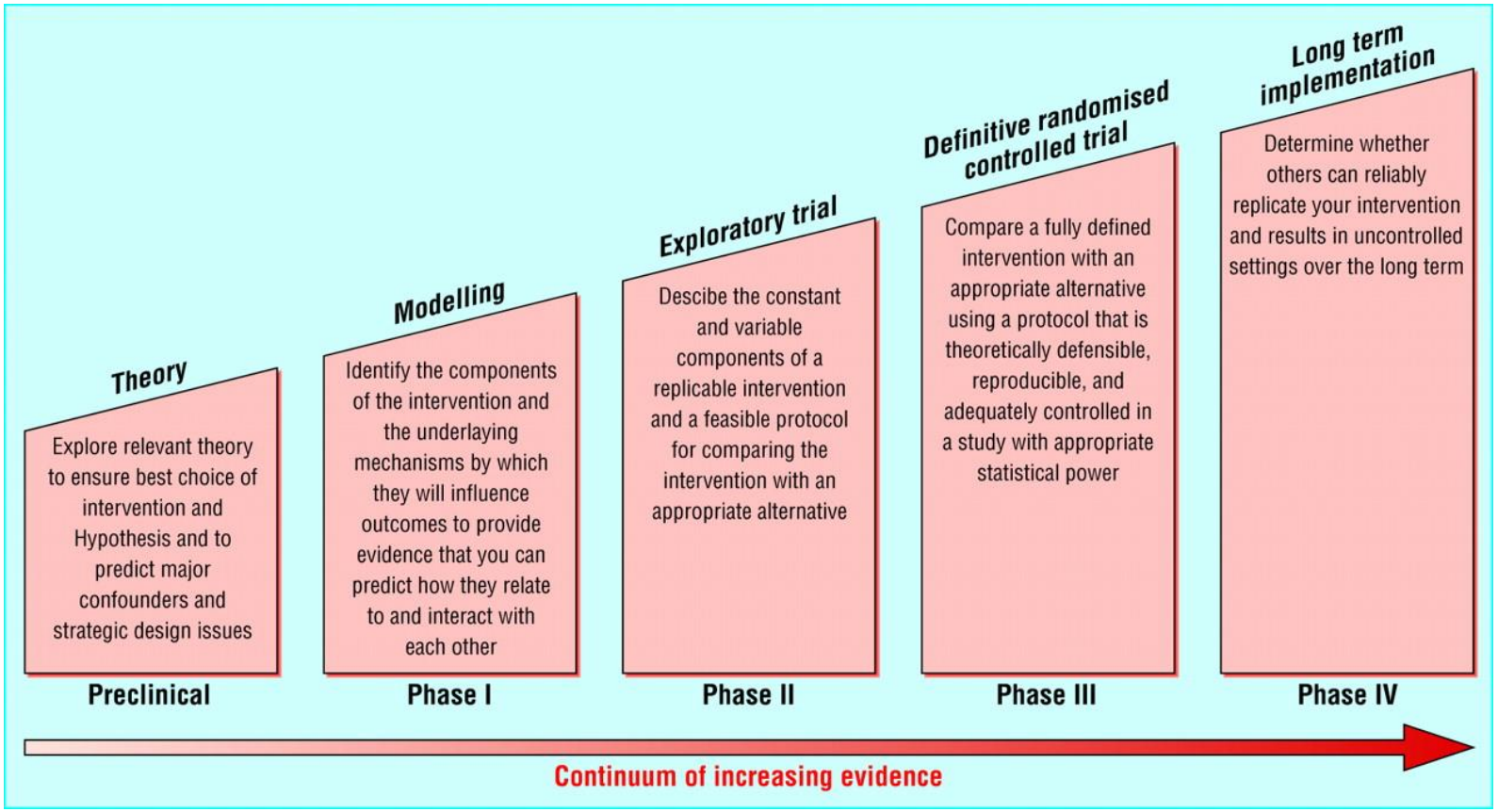
- BIS is a ‘complex intervention’ (series of components: multi-disciplinary professionals delivering multiple interventions)

- Complex interventions:
  - notoriously hard to evaluate
  - notoriously hard to roll-out into the real world

- MRC (2000, 2007, 2008)

  “Framework for the Development & Evaluation RCTs for Complex Interventions to Improve Health”

MRC Framework for Complex Interventions (2000)



Pre-clinical Phase (theory)

- Qualitative study lung cancer & COPD patients' experiences of breathlessness
- Clinical-academic collaboration
- Breathlessness: frightening, disabling & restricting
- Significant suffering among informal carers: severe anxiety, felt helpless & powerless
- Existing services: highly valued, but inconsistent & sporadic

Booth S, Silvester S, Todd C. *Journal of Palliative and Supportive Care* 2003;1(4):337-44

Pre-clinical Phase (theory)

- Results fed into development of pilot BIS:
  - evidence base for need for / role of BIS
  - beginnings of evidence-base for the BIS model (e.g. community-functioning)

- Evidence base for the interventions BIS uses:
  - literature on theories of breathlessness e.g. role of anxiety
  - literature on interventions for breathlessness triggers e.g. anxiety management

Booth S, Silvester S, Todd C. *Journal of Palliative and Supportive Care* 2003;1(4):337-44

Phase I (modelling)

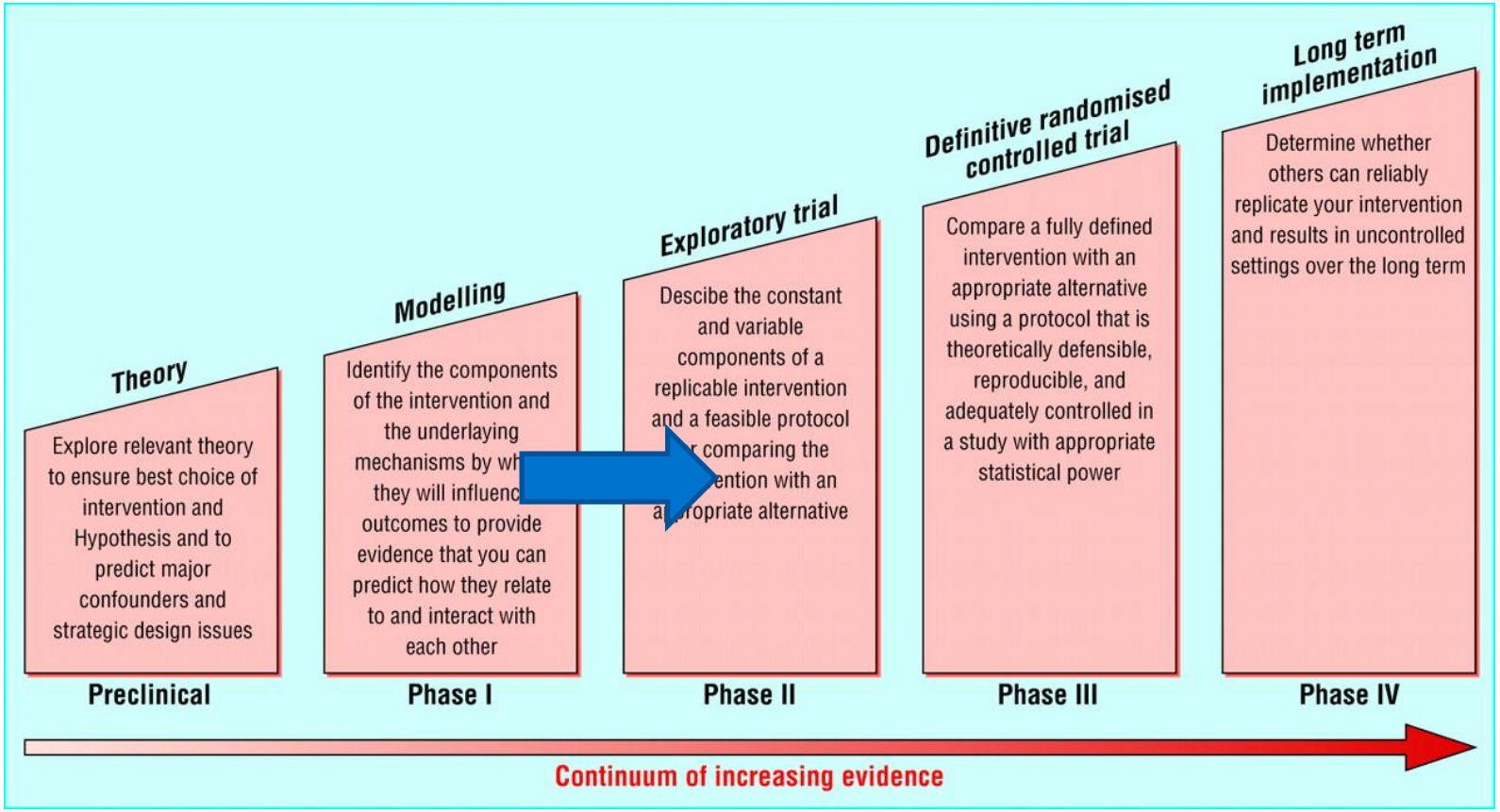
- Pilot service set up (November 2003) based on:
  - pre-clinical empirical findings
  - theoretical underpinning (palliative care model)
  - (growing) evidence-base on individual pharmacological & non-pharmacological interventions for intractable breathlessness
- Qualitative study: users' experience of the pilot service (Summer 2004)
  - patients (n=10) & carers
  - referrers & providers (BIS staff)

Phase I (modelling) – Findings of User Study

- Told us what they liked about BIS & what could be improved (patients, carers & referrers)
- Findings fed back to BIS: led directly to re-modelling of a complex intervention
- Auditable trail of service changes
- Guided choice of RCT outcomes

Booth S, Farquhar M, Gysels M et al. *Jnl Pall Supp Care* 2006; 4(3):287-93

MRC Framework for Complex Interventions



RCTs in Palliative Care

- RCTs: ‘gold standard’ for evaluating services
- BIS: palliative care service
- RCTs notoriously difficult in palliative care - patient recruitment is challenging
  - patients’ ability to participate (both initially & then inevitable deterioration)
  - randomization potentially denies access to the intervention (limited life expectancy) – issue for referrers (gatekeeping) & patients

Fast-track RCT

- Fast-track RCT:
  - ‘fast-track’ group (intervention immediately)
  - ‘control’ group (intervention after waiting list)
  - everyone gets the intervention
- Strength of an RCT, but may be more acceptable to patients & referrers

  Farquhar M, Higginson IJ, Booth S. Fast-Track Trials in Palliative Care: An Alternative Randomized Controlled Trial Design. Jnl Pall Med 2009;12(3):213
- Pragmatic RCT, but…

…Single Blinded – To Reduce Bias

Phase II (exploratory trial)

- Pilot pragmatic single-blind fast-track RCT of the re-developed BIS for COPD patients -v- standard care

- Feasibility study:
  - could we do an RCT of BIS? (palliative care service)
  - and could we learn anything more about BIS?

- Mixed methods RCT:
  - integrated qualitative topic-guided interviews & quantitative outcomes
  - patients (n=13) & carers

- Qualitative interviews:
  - referrers
  - providers (BIS staff)

What Did Phase II Tell Us? – About BIS

- Emphasised value of non-pharmacological strategies & positive, educational approach
- Being seen at home was key (patients, carers, referrers, providers)
- Time & expertise highly valued (patients, carers & referrers)
- Need to further develop assessment of carer need & support

Farquhar M, Higginson IJ, Fagan P, Booth S. Results of a pilot investigation into a complex intervention for breathlessness in advanced chronic obstructive pulmonary disease (COPD): brief report. *Palliat Supp Care* 2010;8(2): 143-9.

Farquhar M, Higginson IJ, Booth S. Modelling the carer support component of a complex intervention for breathlessness in advanced disease. *Palliat Med* 2010;24(4):S167.

Farquhar M, Higginson IJ, Booth S. Referring to a complex intervention for breathlessness, the 'Breathlessness Intervention Service' (BIS): expectations and experiences of referrers of COPD patients. *Palliat Med* 2008; 22 (4): 459-60.

What Did Phase II Tell Us? – About RCT Design

- Fast-track RCT acceptable for patients, carers, referrers & BIS
- Procedures worked (e.g. recruitment & randomisation)
- Single blinding successful – to a point
- Some outcome measures unsuitable

Farquhar M, Higginson IJ, Fagan P, Booth S. The feasibility of a single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease. *BMC Palliat Care* 2009;8:9.

Farquhar M, Ewing G, Higginson IJ, Booth S. The experience of using the SEIQoL-DW with patients with advanced chronic obstructive pulmonary disease (COPD): issues of process and outcome. *Quality of Life Research* 2010;19:619-29.

What Else Did Phase II Tell Us?

- Modify BIS service model:
  - shorten duration of intervention delivery… so RCT protocol could be shorter
- Important finding for a palliative care RCT using fast-track design

Farquhar M, Higginson IJ, Fagan P, Booth S. The feasibility of a single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease. *BMC Palliat Care* 2009; 8:9.

Phase III ("definitive" RCT)

- Pragmatic mixed method single-blind fast-track RCT of BIS -v- standard care for any diagnosis

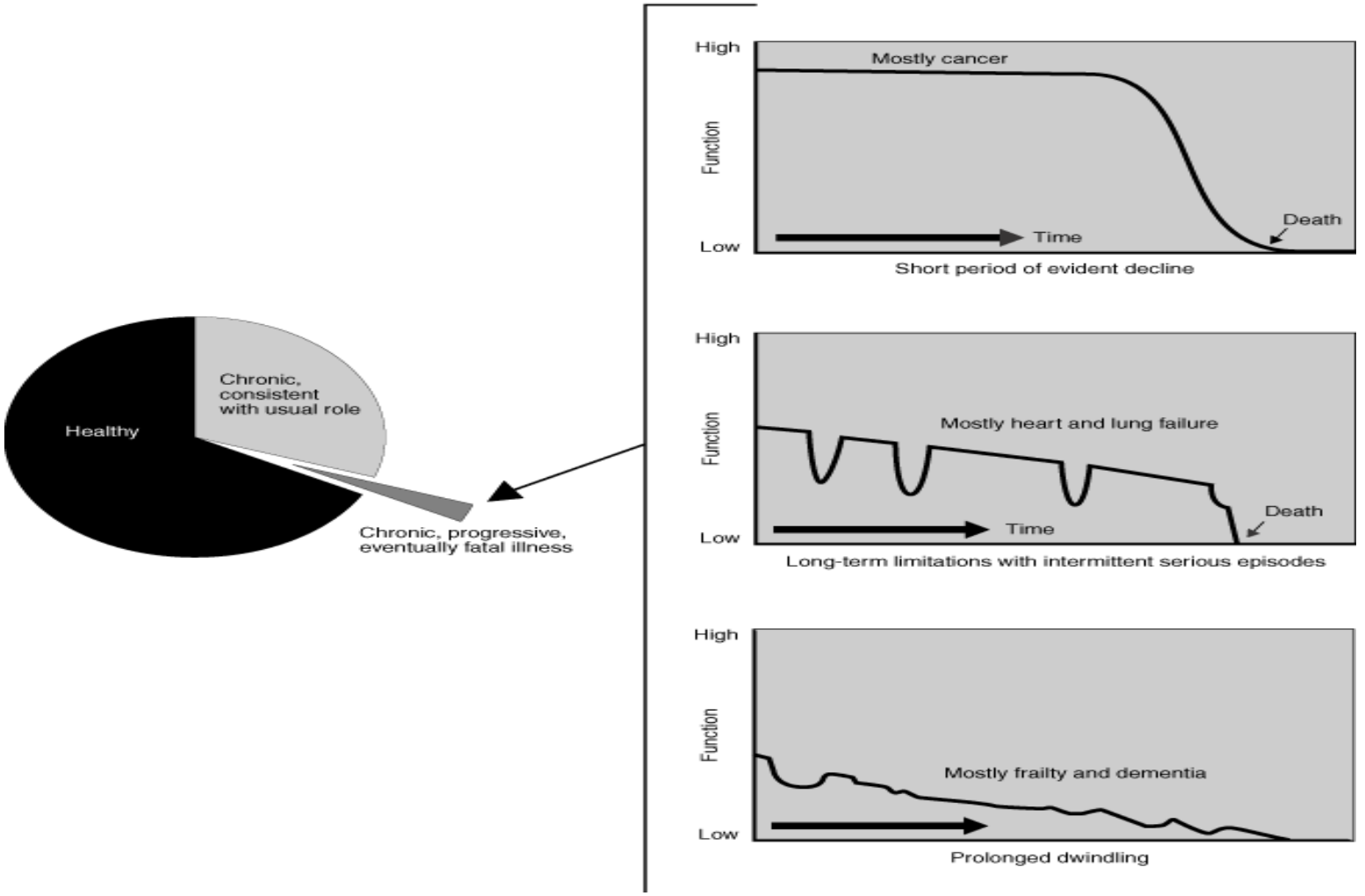
- NIHR RfPB & Macmillan Cancer Support Post-Doctoral Fellowship

- Mixed methods RCT:
  - integrated qualitative interviews & quantitative outcome measures
  - patients (n=130: 60m & 70nm) & carers
  - qualitative interviews: referrers & providers (BIS staff)
  - economic evaluation

Farquhar M, Prevost AT, McCrone P, Higginson IJ, Gray J, Brafman-Kennedy B, Booth S. Study Protocol: Phase III single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease. *Trials* 2011, 12:130.

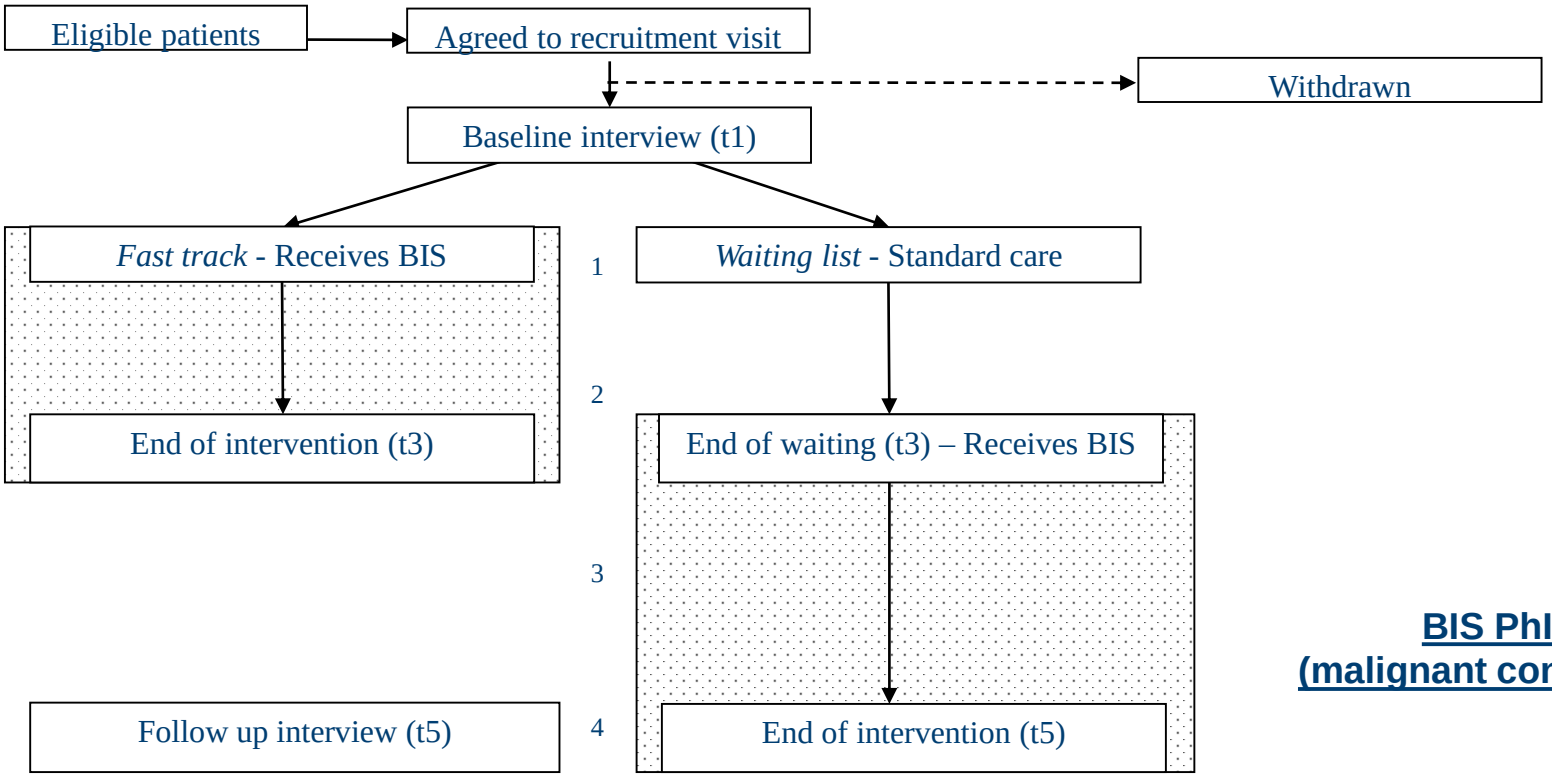
Different Disease Trajectories…

Lynn J (2001) Perspectives on care at the close of life. JAMA 285: 925-932



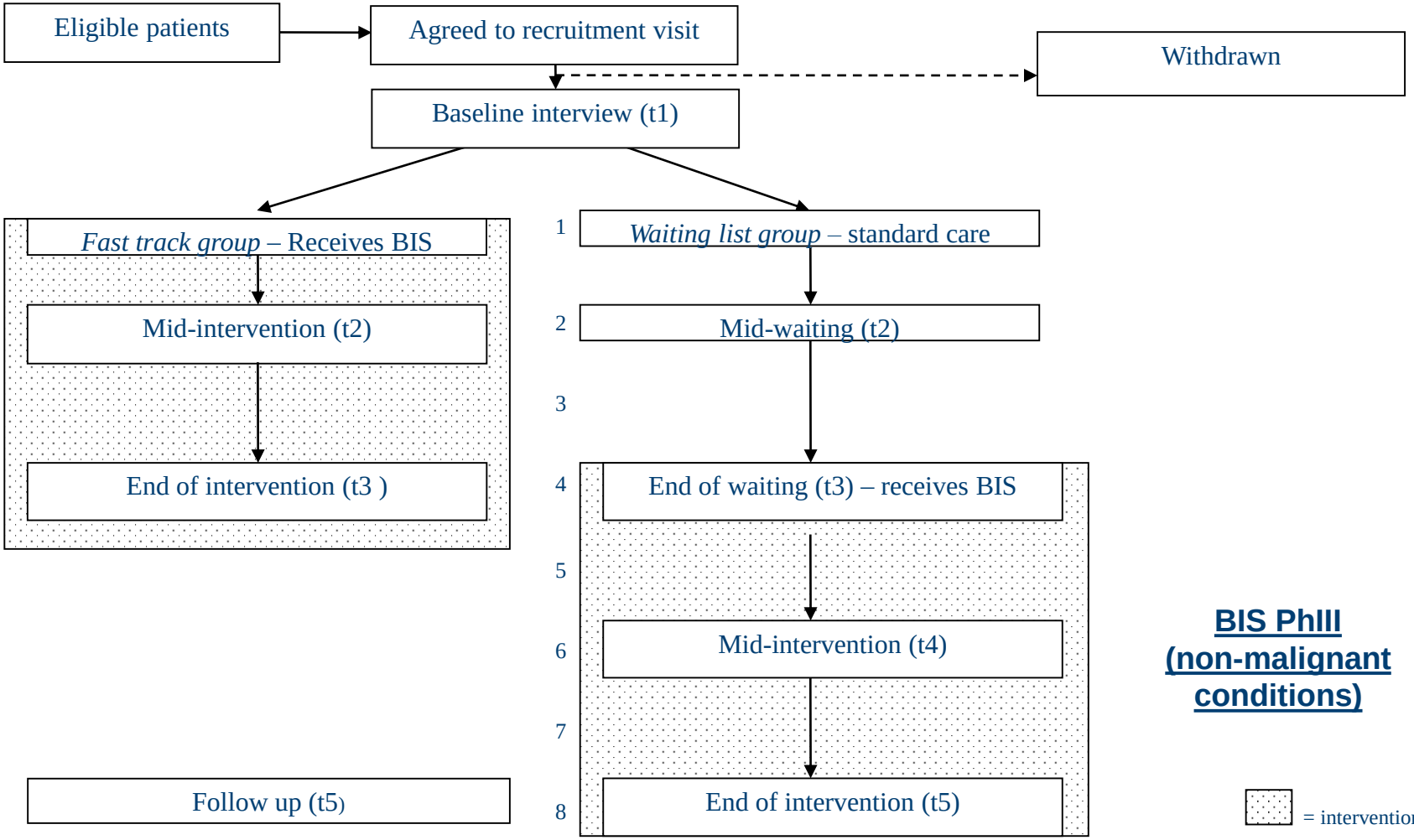
…Differing Service Models by Disease Group

- Patients with non-malignant conditions (e.g. COPD, heart failure):
  - 2-3 visits
  - 2-3 phone calls
  - over 4-week period
- Patients with malignancies (any cancer):
  - 1 visit (ideally with primary care)
  - 2 phone calls
  - over 2- week period
- Two sub-protocols… two RCTs…



BIS PhIII (malignant conditions)

= intervention



BIS PhIII (non-malignant conditions)

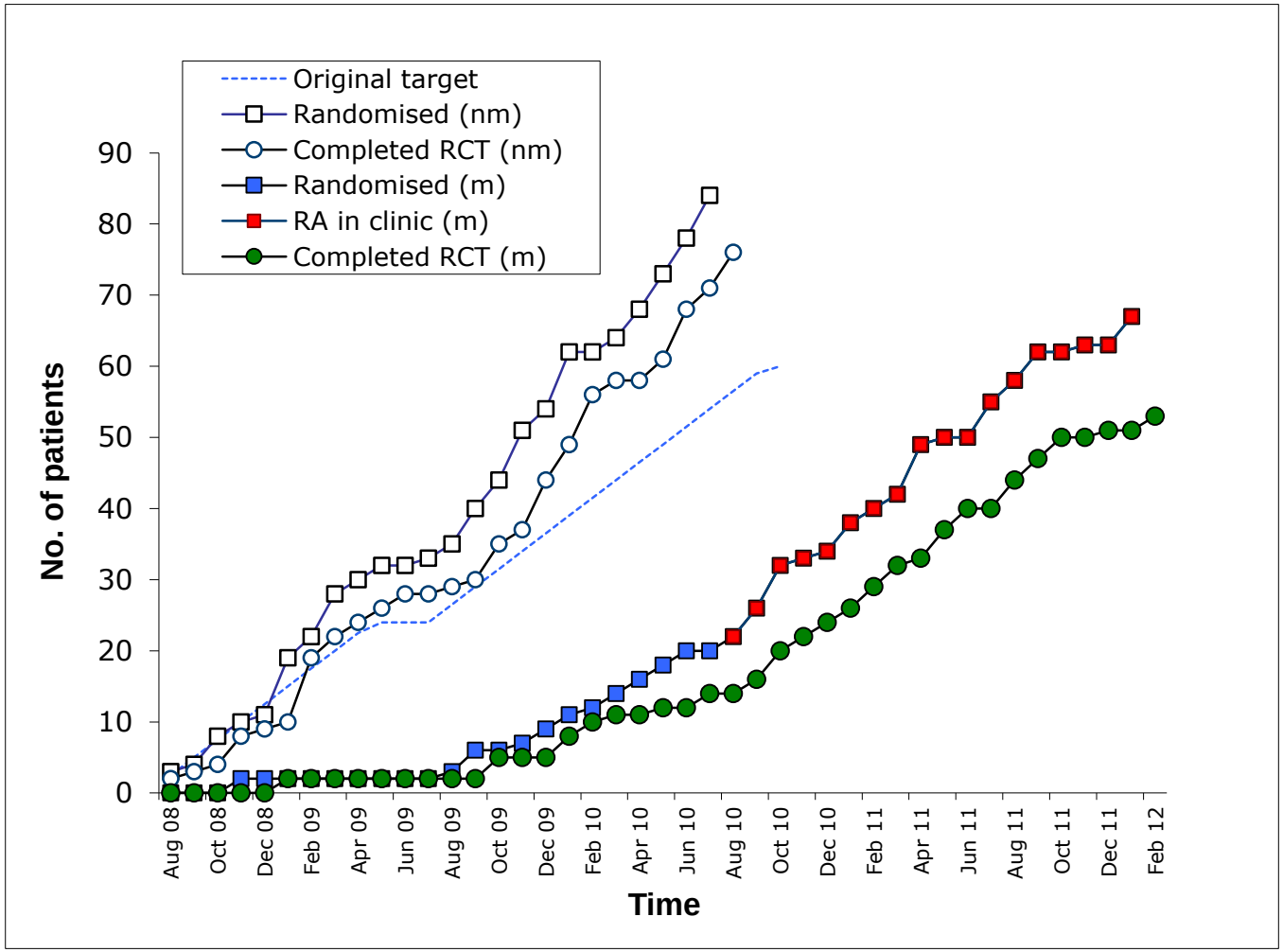
Phase III RCT: Key Patient-reported Measures

- Breathlessness (modified Borg & NRS)
- Distress due to breathlessness (POM) (NRS)
- Anxiety & depression (HADS)
- Disease-specific HRQoL (Chronic Respiratory Disease Q'aire)
- Breathlessness experience & expectations of / satisfaction with BIS (qualitative)
- Economic evaluation:
  - service use (Client Services Receipt Inventory)
  - HRQoL (EQ-5D)

Phase III RCT: Key Carer-reported Measures

- Carer assessment of patient's breathlessness (modified Borg & NRS)
- Carer distress due to patient breathlessness (NRS)
- Carer anxiety & depression (HADS)
- Caring experience & expectations of / satisfaction with BIS (qualitative)
- Caregiver burden (Lawton Appraisal Scale & Zarit Burden Inventory)

Randomized & Completed by Disease Sub-protocol



Phase III RCT: Quantitative Data

- Malignant disease:
  - BIS is effective & cost-effective
  - significantly reduced patient distress due to breathlessness (primary outcome: −1.29; 95% CI −2.57 to −0.005; P = 0.049)
  - 96% of respondents reported a positive impact
- Non-malignant disease:
  - trends in the right direction – no statistically significant differences
  - 92% of respondents reported a positive impact

Phase III RCT: Qualitative Analysis Data

- Purposively sampled:
  - on change in primary outcome measure (“biggest improvers”, “moderate improvers”, “limited improvers” & “worseners”)
  - transcripts from 20 patients and their carers (for each disease group)

- Framework analysis (facilitated by NVIVo) to explore:
  - nature of the impacts of BIS
  - aspects of BIS valued by patients & carers (model & interventions)
  - mechanism of impact

Phase III RCT: Impact of BIS

- Nature of impacts:
  - less frightened, less anxious, less worried, less panicked
  - more confident about their breathlessness
  - true for both disease groups

Phase III RCT: Helpful BIS Interventions

- Handheld fan
- Encouragement of exercise (pedometer and goal-setting)
- Breathing techniques & positioning
- Pacing
- Relaxation (BIS mindfulness-based body scan CD & visualisation techniques)
- Occupational therapy aids
- Learning “being breathless won’t kill me”
- Information (verbal, printed info sheets & hand-drawn diagrams)
- Medication changes
- Referral on to other services (such as hospice day care)
- Daily strategies or tips (“lots of little things”)

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Handheld Fan

"…She's given me a fan, which she drew all pictures [of] and she said 'oh, you're brain's telling this […], and if you try and do this that'll help you'. When she gave me that fan I thought 'well, I don't know', but that does work. I took it up to bed with me and I got puffy and I got to the top of the stairs and I put it on and that was really good. So it's something what I would have disregarded and not given it a thought. That's really good"

536t3pc m; Impact Categorisation Level 1 – Significant impact; Cell 2 – Low Improver on primary outcome measure

Breathing Technique

"She said to me put my lips ... like that ... and [breathe] through my mouth. I thought [...] 'how is that going to work?' […] but I must be honest, it's brilliant. Do you know it helps more than doing it through your nose? […] well I was very interested, because I went to the bathroom and of course when I got back I couldn't breathe […] and I thought 'well give it go', you know, and ... do you know, it does help, it really does. […] and another thing as well, when I get out of breath, is to put my hand on my tummy ... *puff puff puff* ... and do that, and you know, it's amazing really. It sounds so pathetic when you say something... It's simple. It's not a thing you'd think of doing [putting] your hands on your tummy and do that... […] She was really helpful"

530t3pc m; Impact Categorisation Level 1 – Significant impact; Cell 2 – Low Improver on primary outcome measure

“Breathlessness Won’t Kill Me”

I : “…What was the most helpful thing [she] did from your point of view?”

P : “[She told me] breathlessness is not harmful. […] because I thought getting out of breath wasn’t good for you. It’s not good for you, but it’s not going to harm you […] And that reassures you, because if you do get out of breath you think ‘I’m not going to die, this is just a blip, you’ll get over it’ ... […] and now I know what to do. So she was really helpful. I wouldn’t have known that if I hadn’t seen her. I would have just gone on thinking ‘oh dear’ […] And the panic, you see, makes you feel worse. If you’re panicked about something it makes your breathing worse because you breathe different when you panic. Even *you* would if you was in a panic - you would be breathing different. […] and I don’t get that any more. […] I know how to deal with it”.

603t3pc m; Impact Categorisation Level 1 – Significant impact; Cell 1 – Big Improver on primary outcome measure

Phase III RCT: Valued BIS Model

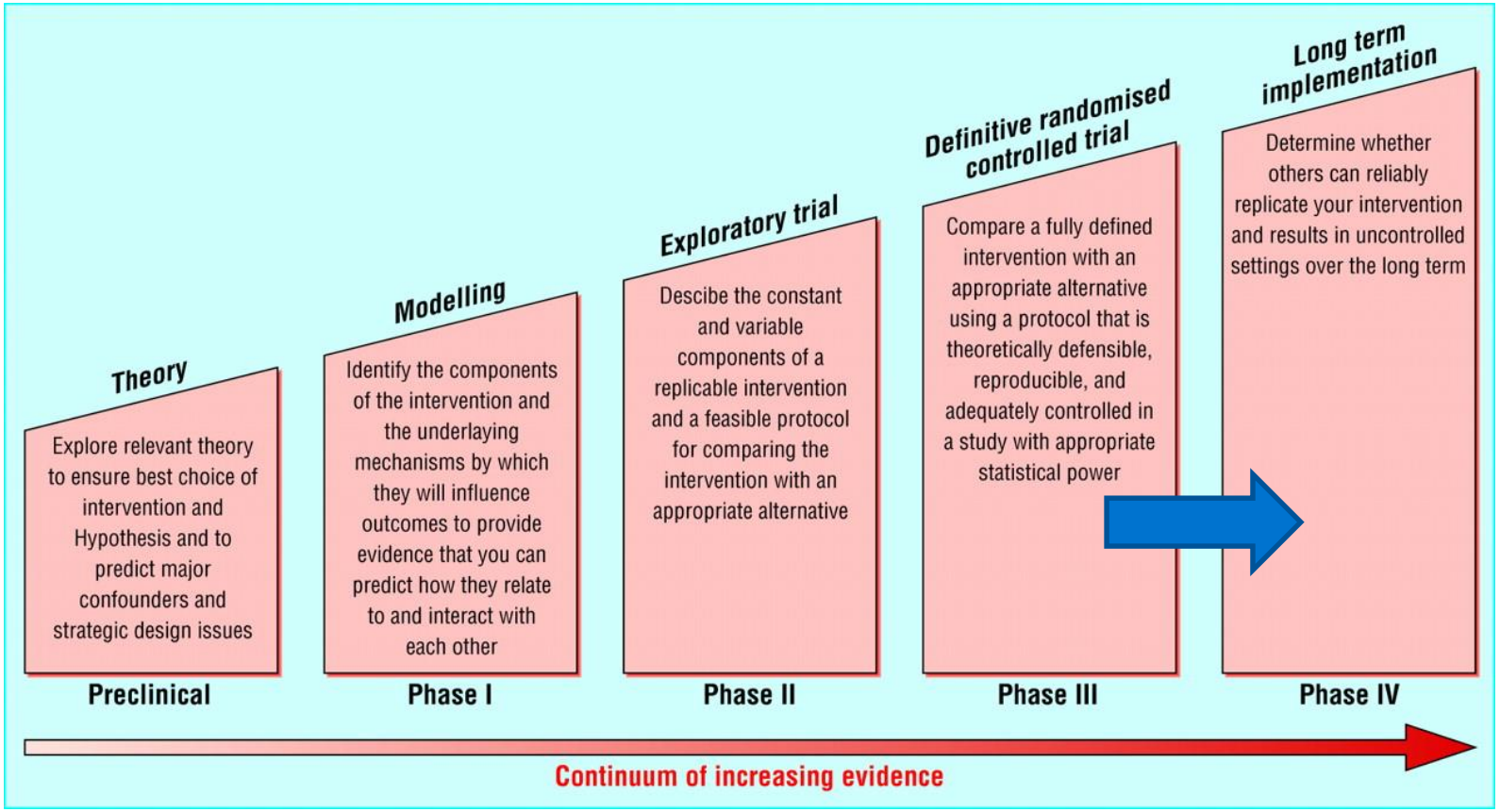
- Multi-disciplinary staff:
  - experts in breathlessness & strategies to manage breathlessness
  - understood life with breathlessness
- Positive staff behaviours: relaxed, easy to talk to, listening skills & reassuring (*how* interventions were delivered was key)
- Time to talk about breathlessness
- Being seen in their own homes
- Positive “can do” approach
- Unexpected attention given to carers

Phase III RCT: Mechanism of BIS Impact

- Mechanisms of impact:
  - **gaining knowledge** about breathlessness
  - enhanced patients' and carers' understanding of symptom & **confidence** in living with it
  - **legitimised** breathlessness (symptom acknowledged by experts)
  - **no longer felt alone**
  - **suggests modulation of central perception**
- True for both disease groups

Farquhar M, Prevost AT, McCrone P, Brafman-Price B, Bentley A, Higginson IJ, Todd C, Booth S. Is a specialist breathlessness service more effective and cost-effective for patients with advanced cancer and their carers than standard care? Findings of a mixed method randomised controlled trial. BMC Medicine 2014 12:194.

MRC Framework for Complex Interventions



What Did This Inspire? (1)

- BIS continues
- BIS roll-out:
  - BIS learning set
  - BIS manual
  - UK BIS-modelled services
    - e.g. Breathlessness Support Service (BSS) King's College London
- INSPIRED!

What Did This Inspire? (2)

- **Programme of research on breathlessness in advanced disease:**
  - Living with Breathlessness study (LWB)
    - Identifying trajectories of patient & carer need in advanced COPD
  - Learning about Breathlessness study (LaB)
    - Developing an educational intervention for carers of patients with breathlessness (COPD & cancer)
  - Two studies in development:
    - Developing, validating & piloting a patient support needs assessment tool for advanced COPD
    - Developing & piloting the Carer Specialist Nurse role for advanced non-malignant disease (COPD & heart failure)

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WE ARE MACMILLAN. CANCER SUPPORT

Thank you

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