The Palliative Care Trial

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Venice, Italy. May, 2006.

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With thanks to the whole team:

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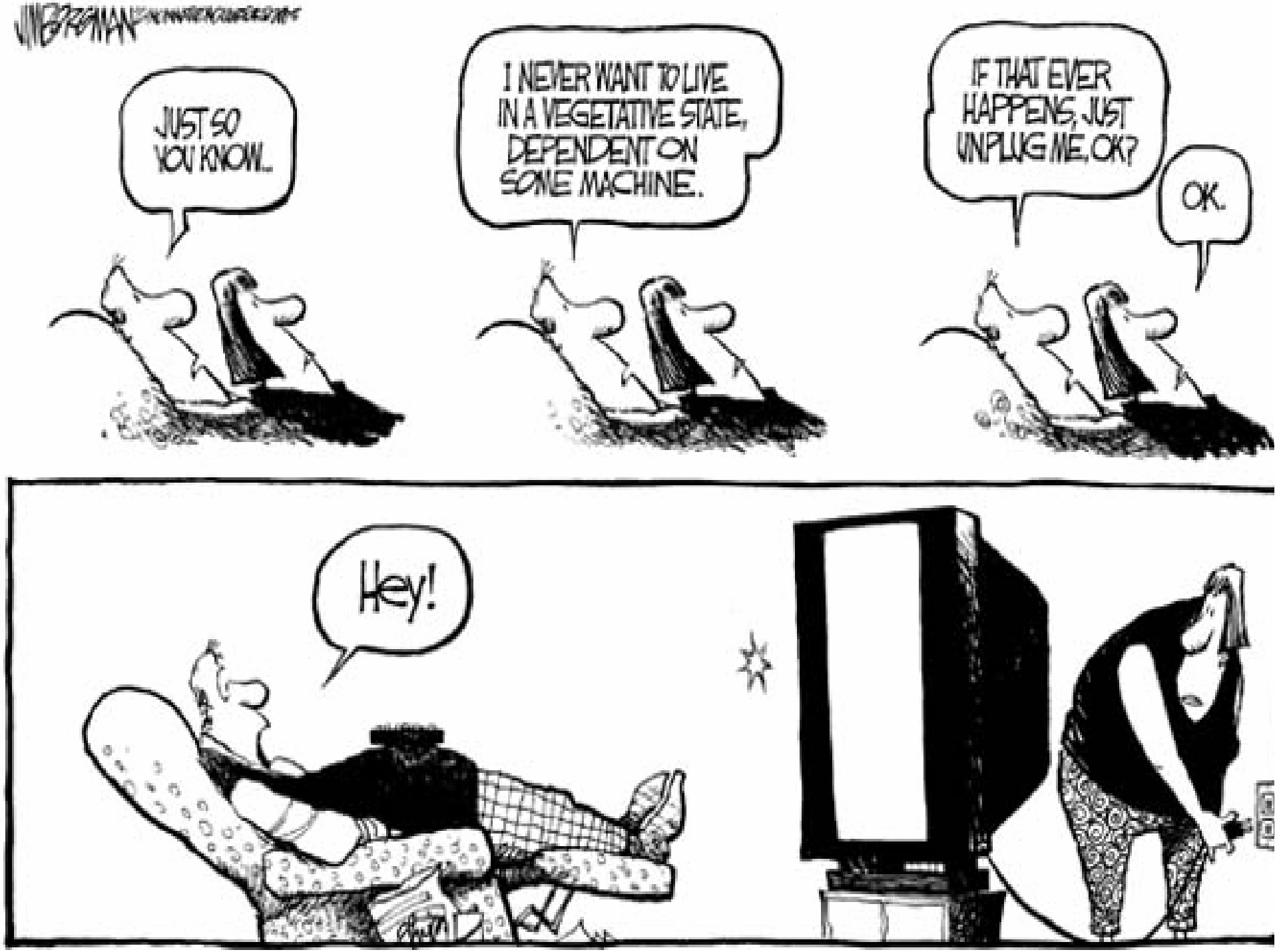
JUST SO YOU KNOW.
I NEVER WANT TO LIVE IN A VEGETATIVE STATE, DEPENDENT ON SOME MACHINE.
IF THAT EVER HAPPENS, JUST UNPLUG ME, OK?
OK.
Hey!

The Palliative Care Trial

1. Design
2. Results
3. Implications of the research

Venice, Italy. May, 2006.

The Palliative Care Trial

1. Design

2. Results

3. Implications of the research

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1. Design

Background –

There is an imperative that we deliver the best possible palliative care with the most effective use of limited resources to the people who most need that support.

There is therefore an imperative that we conduct rigorous studies to evaluate optimising the models of care.

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1. Design

Background –

Palliative care is defined by our ability to optimise level of function and level of comfort in people with advanced life-limiting illnesses.

Maintaining function is a patient-defined and patient-valued outcome.

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1. Design

Cluster* randomised controlled, parallel arm, non-blinded study of case conferencing and educational interventions in a palliative care setting

*** by general practice**

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1. Design

Case Conference Requirements (3:1)

- Interactive discussion
- At least 3 healthcare providers including GP
- Minimum 15 minutes
- Addresses immediate issues, future contingencies

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1. Design

Educational intervention (academic detailing / patient coaching) to help better manage pain* (1:1)

GP or patient***, the factors common to both interventions include:**

- focus on the pain problems of this specific patient

- *a priori,* delivery of evidence-based key messages

- social marketing principles

* Du Pen JCO 1999, de Wit Pain 1997, Weissman JPSM 1996, Ferrell Sem Onc Nurs 1997

** Delivered by a specifically trained doctor

*** Delivered by a specifically trained registered nurse

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1. Design

Setting

Regional whole-of-population consultative specialist palliative care service serving a population of 350,000 people.

1100 referrals per year, 83% of whom have cancer. Mean time from referral to death = 119 days; Median = 47 days

Nursing, medical and allied health staff whose work is entirely in palliative care.

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1. Design
Participants – effectiveness study

People referred to the service:

- pain at some time in the last 3/12
- expected to live > 48 hours
- provide written informed consent
- have their GP provide consent
- live within the service region

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1. Design Interventions

Each participant randomised 3 times

i. One case conference *vs routine care*
ii. Educational outreach visiting (GP) *vs routine care*
iii. Educational outreach visiting (patients + / - their families) *vs routine care*

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1. Design

Participants would therefore be in one of 8 combinations of intervention:

1. Case conference (CC)
2. CC + GP education (GPEd)
3. CC + Patient education (PtEd)
4. CC + GPEd + PtEd
5. GPEd
6. PtEd
7. GPEd + PtEd
8. Routine care

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1. Design

Main outcome measures

1. pain (VAS)
2. functional status (AUC from day 60 until death)
3. resource utilisation including hospitalisations

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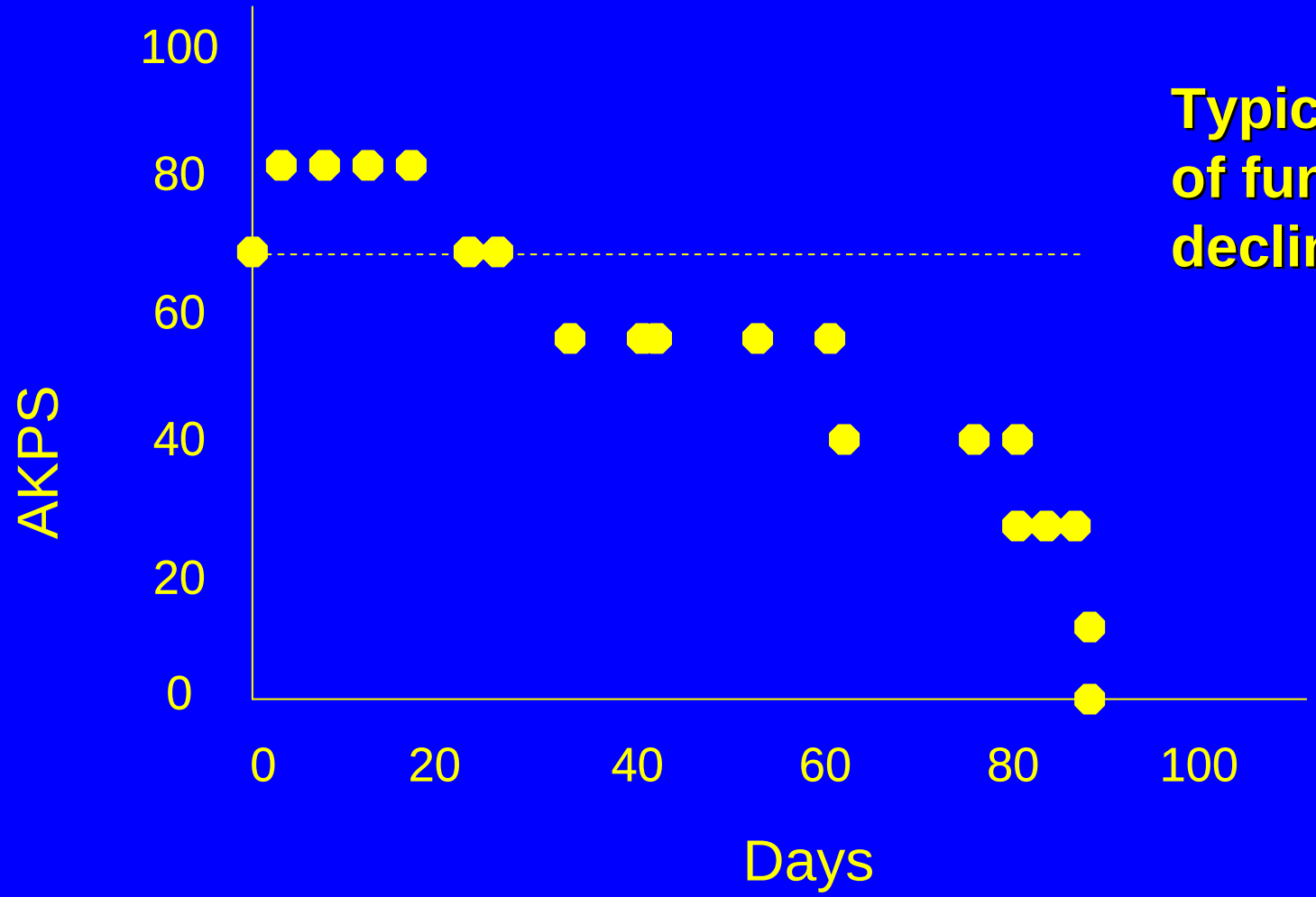

Typical graph of functional decline

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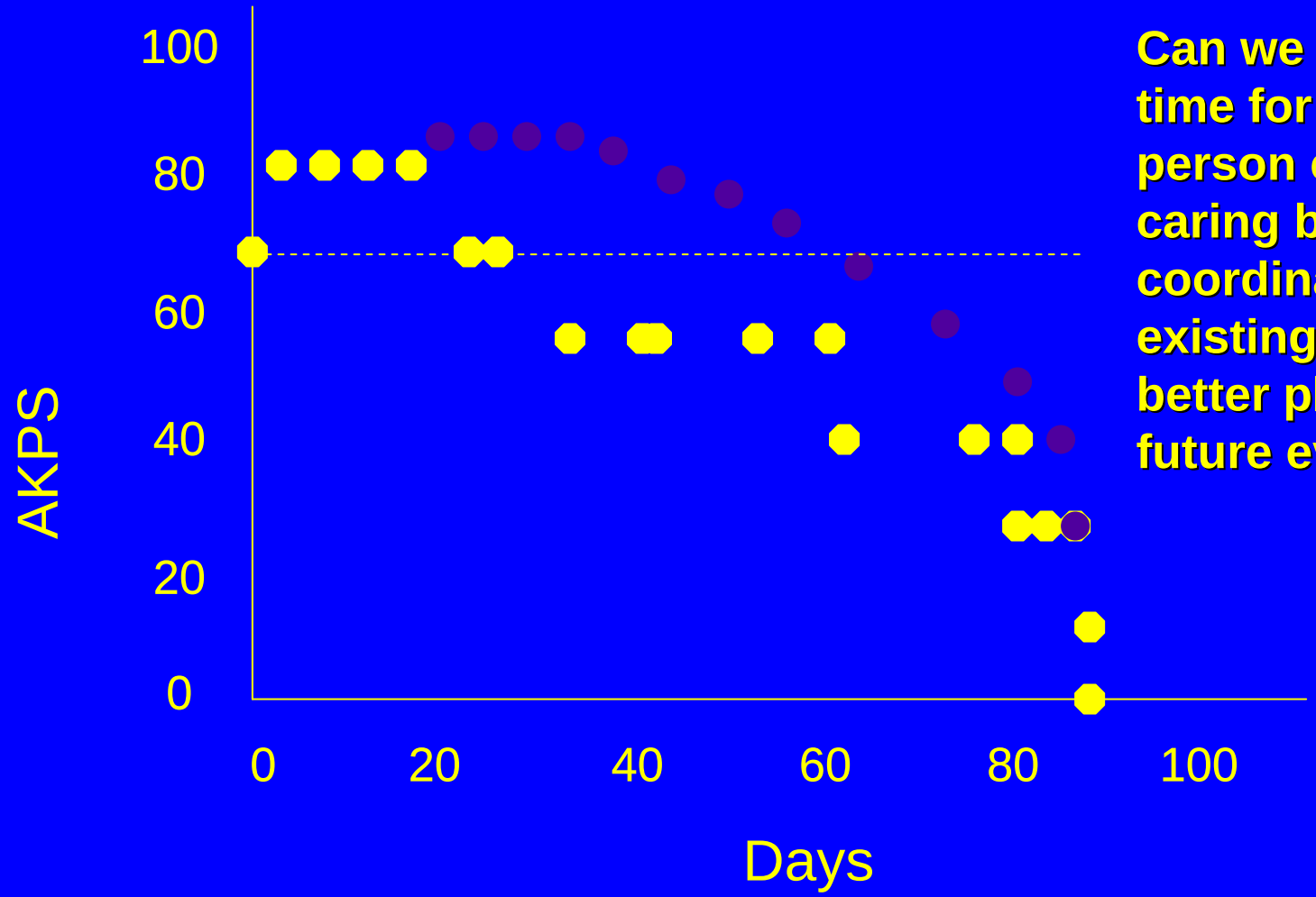

Can we increase the time for which a person can be self-caring by better coordinating existing care and better planning for future eventualities?

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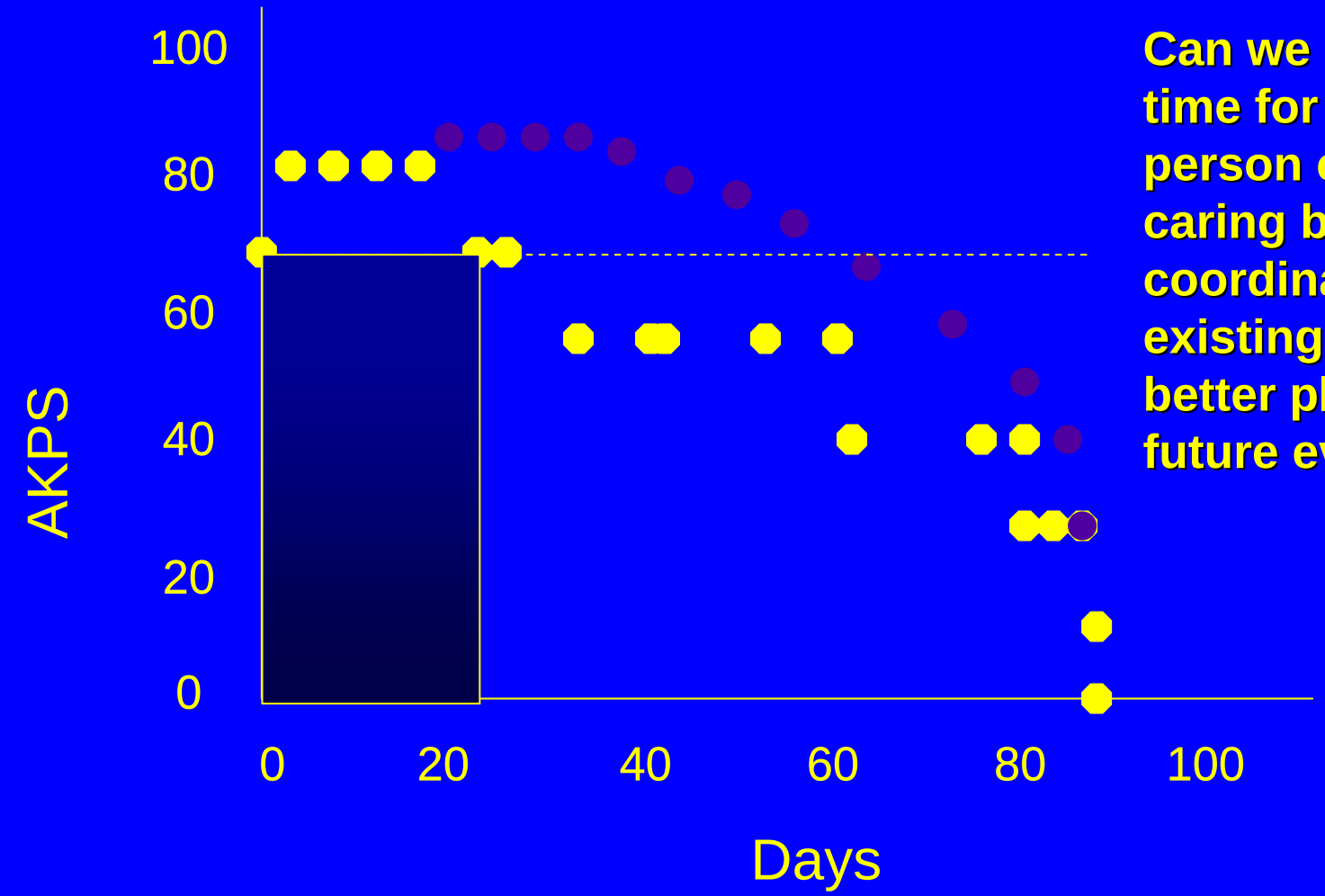

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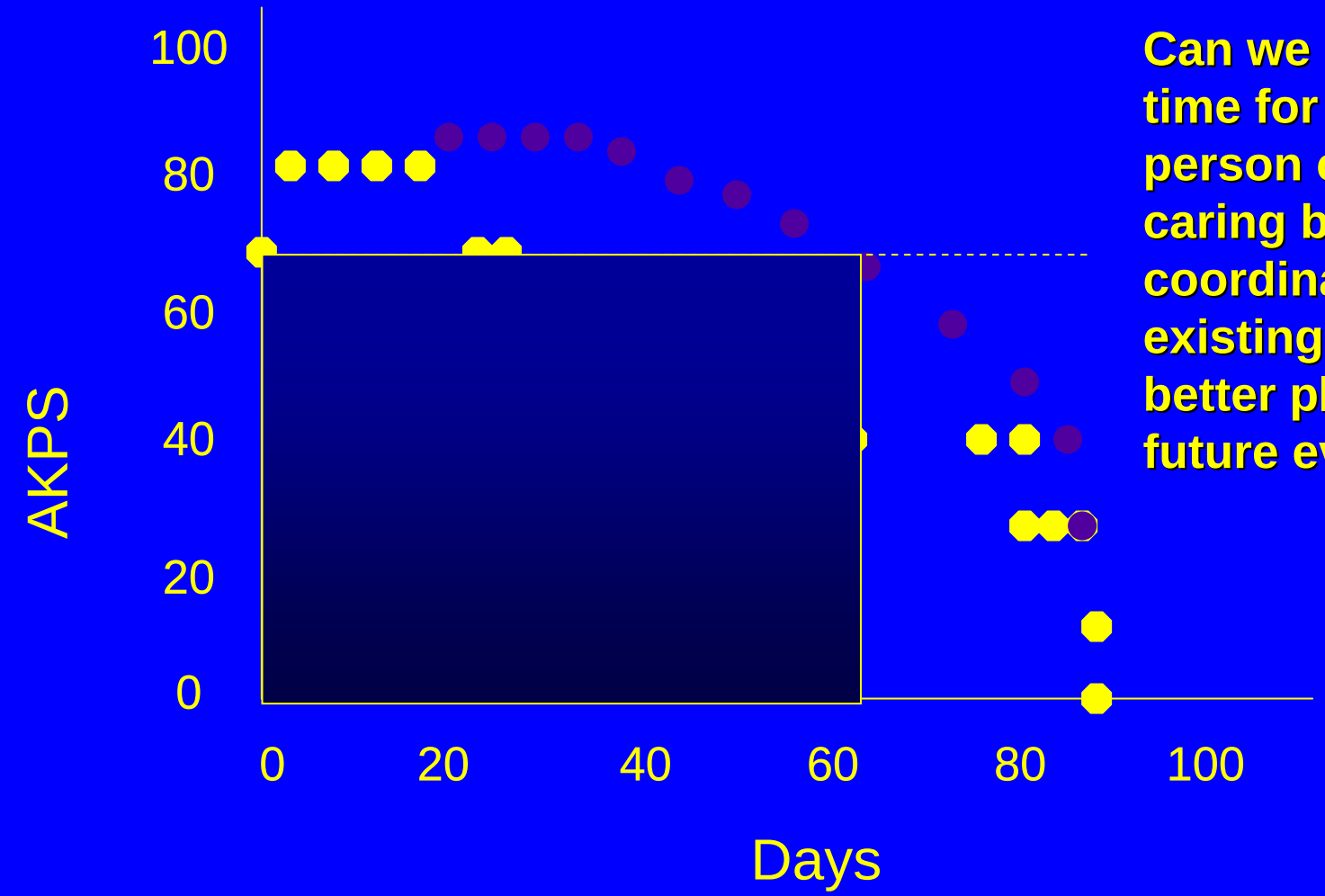

Can we increase the time for which a person can be self-caring by better coordinating existing care and better planning for future eventualities?

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1. Design

Secondary outcome measures

1. Quality of life
2. Symptom distress (constipation, nausea, etc.)
3. Resource utilisation (public and private inpatient and community health service use, subsidised medications, ambulance and Emergency Department use)
4. Place of death
5. At baseline, fortnightly for 3 months and then monthly

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1. Design

Power of the study

- Accounted for expected 59% attrition at 8 weeks (actual 54%)
- Accounts for clustered design (x1.1), factorial design
- Alpha 0.05, 80% power

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1. Design

Analysis

Intention-to-treat

- **Pain - ANOVA**
- **Function - AUC**
- **Resource utilisation – ANOVA**

Randomisation – third party

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1. Design

2. Results

3. Implications of the research

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2. Results

461 participants and their GPs

2,261 referrals to Southern Adelaide Palliative Services

1,948 screened

607 eligible*

500 (82%) of eligible patients consented

461 (92%) of eligible GPs consented

- 342 (74%) died
- 70 (15%) withdrew
- 49 (11%) alive at the end of the trial

*76% of eligible population randomised

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Reasons for withdrawal (N=70)

Paperwork (trial related)	8	11%
Didn't want case conference	2	3%
Other trial related	7	10%
No re-consent at study mid-point	5	7%
Too ill/overwhelmed	9	13%
Doesn't want/need SPCS input	5	7%
Moving out of area	8	11%
Changed GPs	6	9%
Unknown	20	29%

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2. Results

461 participants and their general practitioners completed the study over a 30 month period up to November 2004.

Followed from referral until death, withdrawal or a minimum of 6/12

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2. Results

461 participants

50% male

Mean age 71

91% had cancer as their life-limiting illness

Mean (median) survival from referral to death 146 (87) days

Median baseline Australian-modified Karnofsky Performance Status Score (AKPS)* – 60 (range 20-90)

***Abernethy et al, BMC Pall Care;4:7.**

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2. Results

461 participants

No difference in baseline scores for primary outcome measures in any of the groups

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2. Results

Intervention - one case conference

Outcome - AKPS*

Routine care - 51.7

Case conferencing - 57.3

p=0.0368

* This benefit is most obvious for people who have already started to lose function to the point of needing a caregiver

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2. Results

Intervention - Patient education

Outcome - AKPS*

Routine care - 46.8

Case conferencing - 54.7

p=0.0206

* AKPS <70

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2. Results

Intervention - General practitioner education

Outcome - AKPS

No difference between routine care and the intervention arm

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2. Results

Intervention - Patient education & one case conference

Outcome - AKPS

No additive effect – ? a ceiling

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2. Results

Intervention - One case conference

Outcome - Hospitalisation

Routine care	**- 1.70**
Case conferencing	**- 1.26**
	p=0.0069

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2. Results

Intervention - one case conference
- patient education
- general practitioner education

Outcome - VAS pain

No difference between routine care and intervention arms

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2. Results

Intervention - One case conference
- patient education
- GP education

Outcome - Survival

No differences seen

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2. Results - Limitations

- No blinding

- Single site

- Due to attrition, >50% of palliative care patients will not get a case conference or will die too early to be able to benefit from it

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1. Design
2. Results
3. Implications of the research

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3. Implications of the research
... for the clinical service.
Redesigning care

- Single entry point to the service
- Triage by a single clinician of all referrals
- Re-design of key documentation / data collection (2 million data points)
- Conversations about outcomes

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3. Implications of the research ... for the clinical service.

Service relationships

Specific partners include:

- District nurses
- Community allied health
- Division of general practice
- Funders
- Private insurers

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3. Implications of the research ... for future research.

- Good research costs real money (AU$2M)
- Factorial design – an economy of scale – the infrastructure is in place, the data are already being collected (don't try this at home without someone else present)
- sub-studies *a priori*

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3. Implications of the research ... for future research.

- Objective outcome measures that are understood by health planners and health funders. (We do make a difference and we can demonstrate it)
- Objective outcome measures that are valued by participants

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3. Implications of the research

... for future research.

Research infrastructure

- Need for adequately funded research planning

-Accuracy of pilot study that includes feasibility and power calculations

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3. Implications of the research ... for future research.

Research infrastructure

- Authorship protocol
- Recruitment and retention protocols including dedicated recruitment staff
- Data collection mechanisms integrated into routine clinical care

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3. Implications of the research

... for health policy (not limited to palliative care)

One of only 4 RCTs that explore the use of case conferencing in the whole health system.

(2 are in palliative care)

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Conclusion

Research in the day-to-day delivery of palliative care can provide opportunities for improved patient function and decreased resource utilisation through adequately tested innovations in service delivery with ongoing collateral benefits to the service & the sector

Life should not be a journey to the grave with the intention of arriving safely, in an attractive well preserved body.

But rather to skid in sideways, champagne in one hand, strawberries in the other, body thoroughly used up, totally worn out and screaming 'WOO-HOO! What a ride!'

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