Umeå universitet
Institutionen för kost- och måltidsvetenskap

KOD

Kunskapsprov för dietister

DELPROV 1

SKRIV DIN PERSONLIGA KOD I RUTAN PÅ VARJE SIDA!

Datum: 2024-01-19

Tid: 08.00 – 14.00

Hjälpmedel: Miniräknare och kladdpapper

Instruktioner

Provet består av 110 frågor där majoriteten av frågorna är flervalsfrågor. Vid flervalsfrågorna är ett svarsalternativ rätt. Läs frågorna noggrant.

Om ett eller flera svarsalternativ är felaktigt ikryssade eller om ett korrekt svar inte är ikryssat ges noll poäng på frågan.

Bilagor finns i separat dokument.

DEL 1 Medicinsk terminologi och magtarmkanalens fysiologi
DEL 2 Dietetik med sjukdomslära, kost och folkhälsa samt näringslära
DEL 3 Analys av vetenskaplig artikel

Kravgräns:

För godkänt på delprovet krävs att **88 av frågorna** är korrekt besvarade.

DEL 1

1. En av rekommendationerna för kostfiberintag i NNR6 2023 är:

- [ ] 25–30 g kostfiber/dag
- [ ] 3–3,5 g/MJ/dag
- [ ] 3,5 g/MJ/dag

2. Vad betyder ordet Kosher?

- [ ] Ordet representerar det som är tillåtet att ätas av rättrogna judar, ordet hänvisar också till sättet som mat produceras och tillagas.
- [ ] Ordet representerar troende muslimers fastemånad
- [ ] Ordet representerar det som är tillåtet att äta inom buddhismen

3. Vad innebär begreppet pica?

- [ ] Att vara selektiv mot livsmedel
- [ ] Att känna sug och konsumera sådant som inte är livsmedel
- [ ] Att matvägra

4. Vilka kliniska symtom ger atopisk dermatit?

- [ ] Rinnsnuva, nästäppa och nysningar
- [ ] Seg saliv och sväljsvårigheter
- [ ] Klåda och utslag på huden

DEL 1

5. Vad står förkortningen ARFID för?

- [ ] Advanced Rumination Food Intake Disorder
- [ ] Avoidant Restrictive Food Intake Disorder
- [ ] Alternative Regulatory Functions in Intake and Digestion

6. ATP är slutprodukten vid oxidation av energigivande näringsämnen. ATP används som energi i kroppen i olika former. Vilket av nedanstående påståenden är korrekt?

- [ ] Elektrisk energi, kan vara till exempel muskelkontraktioner
- [ ] Mekanisk energi, kan vara till exempel överföring av nervimpulser
- [ ] Kemisk energi, kan till exempel handla om värmeproduktion

7. Värdet för Physical activity level (PAL) kan beräknas på detta sätt:

- [ ] TEE/REE
- [ ] BMR/TEE
- [ ] REE/TEE

8. Vad av följande är CRP?

- [ ] En kostundersökningsmetod
- [ ] En inflammationsmarkör
- [ ] En fettsyra

DEL 1

9. Vad är ett annat ord/beskrivning av stenos?

- [ ] Rodnad
- [ ] Celldöd
- [ ] Förträngning

10. Vad innebär intravenös tillförsel?

- [ ] Tillförsel via blodbanan
- [ ] Tillförsel via magtarmkanalen
- [ ] Kombinerad tillförsel via magtarmkanal och blodbana

11. Vilket begrepp stämmer överens med följande beskrivning? Metabol överbelastning till följd av för hög näringstillförsel.

- [ ] Wernicke-Korsakoffs syndrom
- [ ] Beriberi
- [ ] Refeeding syndrom

12. Vilken är den gemensamma nämnaren som anses främst vara den bidragande orsaken till att metabolt syndrom utvecklas?

- [ ] Höga blodfetter
- [ ] Insulinresistens
- [ ] Förhöjt blodtryck

DEL 1

13. Vad är geriatrik?

- [ ] Läran om sjukdomar hos äldre personer
- [ ] Kirurgiskt borttagande av magsäcken
- [ ] Inflammation i njurens glomeruli

14. Vad är agnosi?

- [ ] Halvsidesförlamning hos en person
- [ ] Svårighet att känna igen saker och personer
- [ ] Minskad muskelmassa hos en person

15. Vad avses med textur?

- [ ] Fettinlagring
- [ ] Kirurgisk söm
- [ ] Struktur och uppbyggnad

16. Vilket påstående gällande infektion är korrekt?

- [ ] En infektion kan leda till inflammation
- [ ] En infektion kan orsakas av bakterier, en inflammation eller virus
- [ ] En infektion leder alltid till sjukdom

DEL 1

17. Vad är spirometri?

- [ ] Används för att mäta pulsen vid fysisk aktivitet
- [ ] Används för att bedöma andningsförmågan
- [ ] Används för att bedöma bentätheten

18. Vad är ett annat ord/beskrivning av hypogeusi?

- [ ] Minskad smakförnimmelse
- [ ] Minskad känsel
- [ ] Minskad rörlighet

19. Vad är peritonealdialys?

- [ ] Dialys via vena cava superior
- [ ] Dialys via graft i underarm
- [ ] Dialys via bukhinnan

20. Vad är ett annat ord/beskrivning av striktur?

- [ ] Kroppsöppning
- [ ] Sjuklig förträngning av rörformig anatomisk struktur
- [ ] Icke-normal förbindelse mellan två organ

21. Vad är steatos?

- [ ] Blodansamling i munslemhinnan
- [ ] Kirurgiskt anlagd öppning/förbindelse
- [ ] Inlagring av fett i levern

22. Kronisk pankreatit karaktäriseras av:

- [ ] Återkommande attacker av långvarig smärta i buken
- [ ] Fatigue och steatorré
- [ ] Illamående och diffus obehagskänsla i epigastret

23. När behövs en permanent ileostomi skapas?

- [ ] När sista delen av tjocktarmen, ändtarmen och ändtarmsöppningen inte längre fungerar som den ska
- [ ] När hela eller större delar av tjocktarmen måste opereras bort
- [ ] När tarmen tillfälligt behöver avlastas

24. Dumping är en komplikation som kan förekomma framför allt vid:

- [ ] Colonresektion
- [ ] Pankreasresektion
- [ ] Ventrikelkirurgi

DEL 1

25. Vilket av följande organ är inte beroende av insulin för att ta upp glukos?

- [ ] Hjärta
- [ ] Pancreas
- [ ] Fettväv

26. Vad betyder gastropares?

- [ ] Fördröjd magsäckstömning utan mekaniska hinder
- [ ] Fördröjd magsäckstömning med mekaniska hinder
- [ ] Fördröjd magsäckstömning

27. Vad är gluten?

- [ ] Samlingsnamn för kolhydrater som finns i vete, korn och råg
- [ ] Ett namn som representerar personer som inte tål vete, korn och råg
- [ ] Samlingsnamn för proteinfraktionen som finns i vete, korn och råg

28. Vilket av följande tillstånd kan vanligen INTE påverka ett barns tillväxt?

- [ ] Celiaki
- [ ] Glaukom
- [ ] Turners syndrom

DEL 1

29. Vid amning utlöses *sugreflexen* av följande beröring:

- [ ] Beröring av tunga, gom, papilla incisivae
- [ ] Beröring av munvinklar och kinder
- [ ] Beröring av främre gombågarnas nedre del

30. Vad betyder sucking?

- [ ] Barnets sugmönster rör sig framåt - bakåt
- [ ] Barnets sugmönster rör sig uppåt - neråt
- [ ] Barnets sugmönster är en kombination av framåt - bakåt och uppåt -neråt

31. Vilken är den korrekta betydelsen av PKU?

- [ ] Proteinketonuri
- [ ] Postkardiell uremi
- [ ] Phenylketonuria

32. Vad är latinska ordet för tolvfingertarmen?

- [ ] Duodenum
- [ ] Jejunum
- [ ] Ileum

33. Ett annat ord för en onaturlig rörformad kanal i magtarmkanalen är:

- [ ] Varicer
- [ ] Ulcus
- [ ] Fistel

34. Vilket av nedanstående punkter anger det verksamma ämnet i läkemedel som skrivs ut för att motverka obesitas?

- [ ] Liraglutid
- [ ] Paracetamol
- [ ] Amlodopin

DEL 2

35. Hur mycket grönsaker och frukt rekommenderas barn och ungdomar över 10 år att äta dagligen enligt nordiska näringsrekommendationer (NNR 2023)?

- [ ] 400–600 gram
- [ ] 600–800 gram
- [ ] 500–700 gram

36. För vilket av följande näringsämnen höjdes rekommendationen för vuxna i de senaste näringsrekommendationerna (NNR2023)

- [ ] B12
- [ ] Vitamin D
- [ ] Järn

37. Vilket av nedanstående påstående om protein är korrekt?

- [ ] De essentiella aminosyrorna finns inte i tillräcklig mängd i en vegankost
- [ ] Proteinbehovet ökar när energiintaget överstiger energiförbrukningen
- [ ] Ett protein kan ha hög proteinpoäng men samtidigt vara en dålig källa till protein

38. Vilken av nedanstående aminosyror INTE en grenad aminosyra?

- [ ] Valin
- [ ] Histidin
- [ ] Leucin

DEL 2

39. När en graviditet planeras rekommenderas kvinnan att ta tillskott av

- [ ] Vitamin D
- [ ] Järn
- [ ] Folat

40. Du äter en vegankost och behöver öka ditt kalciumintag. Vilket av följande livsmedel skulle du då välja i första hand?

- [ ] Grönkål
- [ ] Spenat
- [ ] Ruccola

41 Patienten, Kvinna 42 år, BMI 19, har remitterats till dig för ofrivillig viktnedgång. Patienten kommer från Irak och har bott i Sverige i två år. Vid samtalets början noterar du att patienten bär slöja. Hur visar du kulturell hänsyn:

- [ ] Bortser från vad du noterat utifrån remiss och vad du iakttar när ni träffas, du fokuserar på frågar kring måltidsordning och hur stora portionerna är.
- [ ] Tar för givet att patienten varken äter fläskkött eller dricker alkohol på grund av religiösa skäl, utan att fråga patienten.
- [ ] Frågar upp hur patientens matvanor ser ut, vad patienten tycker om och vad hon undviker.

42. Patienten är vegan och har frågor kring protein i en vegankost. Vilket av nedanstående rekommendation är korrekt?

- [ ] Uppmuntra till att äta baljväxter och cerealier vid samma måltid och i tillräcklig mängd för att säkerställa proteinbehovet.
- [ ] Uppmuntra patienten att äta baljväxter och cerealier/ris regelbundet och i tillräcklig mängd varje dag, det behöver dock inte vara i samma måltid. Säkerställ att energibehovet täcks.
- [ ] Lugna patienten, rekommendera patienten att äta tillräckligt mycket energi eftersom det kommer att säkerställa att proteinbehovet täcks.

DEL 2

43. Vilket av följande kriterier ingår i diagnosen ARFID?

- [ ] Kroppsfixering
- [ ] Kompensatorisk beteende
- [ ] Behov av sondnäring eller näringstillskott för att bibehålla kroppsvikten

44. Vilket energibehov enligt nedan stämmer bäst överens med det totala energibehovet för en kvinna, 40 år (vikt 68 kg) som har en fysisk aktivitetsnivå (PAL) på 1,8. Använd tabell i Bilaga 1.

OBS! Ströks från provet eftersom längd inte var angivet i frågan.

- [ ] 2400 kcal
- [ ] 2600 kcal
- [ ] 2800 kcal

45. Energiförbrukningen för en timmes aktivitet för Kalle, 30 år som väger 70 kg och utför en aktivitet som motsvarar MET-värde 6 kan skattas till

- [ ] 420 kcal
- [ ] 300 kcal
- [ ] 380 kcal

46. Hur bör man gå tillväga för att beräkna energibehovet (för viktstabilitet) hos en patient med övervikt?

- [ ] Använda sig av den kroppsvikt som motsvarar BMI 22 med tillägg av 20% av den överskjutande vikten
- [ ] Använda sig av den kroppsvikt som motsvarar BMI 25 med tillägg av 25% av den överskjutande vikten
- [ ] Använda sig av den kroppsvikt som motsvarar önskvärt BMI

DEL 2

47. Vilket av nedanstående mikronutrient är vanligt kosttillskott för en gravid i tredje trimestern?

- [ ] Vitamin A
- [ ] Folsyra
- [ ] Järn

48. Vilket är det primära immunoglobulinet som är involverat i allergiska reaktioner?

- [ ] IgA
- [ ] IgE
- [ ] IgM

49. Vilken typ av allergisk reaktion kan förekomma inom några minuter efter intag av ett allergen och karakteriseras av symtom som klåda, svullnad och andningsbesvär?

- [ ] Allergisk rinit
- [ ] Eosinofil esofagit
- [ ] Anafylaxi

50. Du träffar en flicka som är 6 månader som nyligen har fått en knapp (gastrostomi). Du ombeds göra ett uppstartschema för sondmatning. Vilken av följande sondnäringar rekommenderar du?

- [ ] Infatrini
- [ ] Isosource junior energy
- [ ] Nutrini peptisorb

DEL 2

51. Vad av nedan stämmer gällande parenteral nutrition?

- [ ] Perifer venkateter är att föredra om den parenterala nutritionen är planerad under lång tid
- [ ] Parenteral nutrition kan användas som nutritionsstöd samtidigt som enteral nutrition
- [ ] Parenteral nutrition kan aldrig användas som enda nutritionsstöd

52. Vid parenteral nutrition (PN), varför är det viktigt för en dietist att veta om patienten har central eller perifer venkateter?

- [ ] Styr om PN lösningen kan vara energi- och näringsmässigt komplett
- [ ] Styr vilket typ av proteinkälla som kan användas i PN lösningen
- [ ] Styr vilken osmolaritet PN lösningen kan ha

53. Alkoholintag och insulinbehandlad diabetes - vilket av nedanstående påståenden är korrekt?

- [ ] Alkohol ökar risken för hyperglykemi eftersom alkohol till viss del absorberas direkt via ventrikelns slemhinna
- [ ] Alkohol blockerar glukoneogenesen i levern vilket ökar risken för hypoglykemi
- [ ] Alkohol blockerar glykogenolysen i levern vilket ökar risken för hypoglykemi

54. Vilka av nedanstående är livsmedel som alla är naturligt glutenfria?

- [ ] Bulgur, Havre, Teff, Råris
- [ ] Grahamsmjöl, Durummjöl, Mandelmjöl, Majsmjöl
- [ ] Potatismjöl, Rismjöl, Tapioka, Bovete

DEL 2

55. Du ska träffa en 22 månaders pojke på barnmottagningen och får en anamnes av sjuksköterskan inför mötet. Vilket av följande påstående kan vara korrekt, utifrån den information tillväxtkurvan ger dig? Se bilaga 2

- [ ] Barnet har sedan införande av smakportioner och fast föda haft svårt att få i sig tillräckliga mängder mat
- [ ] Barnet hade en catch-up vid fyra månaders ålder och följer sin egen viktkurva
- [ ] Barnet föddes liten för sin ålder (SGA) men har för åldern en symmetrisk tillväxt

56. Titta på tillväxtkurvan och på barnets vikt. Vad kallas viktökning som skett under barnets första tre levnadsmånader? Se bilaga 3

- [ ] Återhämtningstillväxt
- [ ] Amningspuckel/Tillväxtpuckel
- [ ] Intrauterina tillväxtperioden

57. Vilket av nedanstående påstående är rätt angående modersmjölkersättning?

- [ ] Det går bra att blanda egen modersmjölkersättning av mjölk, några droppar olja tillsätts
- [ ] Det rekommenderas inte att kombinera flaskmatning och amning
- [ ] Modersmjölksersättning finns att köpa i matvarubutiker och på apotek

58. Vilket av nedanstående påstående är korrekt angående smakportioner till små barn?

- [ ] En smakportion av livsmedel motsvarar i mängd ungefär ett som ett kryddmått, smakportionen ges med sked eller på fingertoppen så att barnet kan smaka
- [ ] Smakportion ska endast ges under lunchtid för att inte inkräkta på amning/flaskmatning
- [ ] Vid introduktion av smakportioner bör en livsmedelsgrupp i taget införas

DEL 2

59. Vilka av nedanstående näringsämnen är det vanligt att substituera med vid cystisk fibros?

- [ ] Tiamin, Niacin och järn
- [ ] Vitamin B12 (kobalamin) och Kalcium
- [ ] Vitamin A, D, E, K

60. Vilken av nedanstående tillsats behöver en person med PKU vara uppmärksam på?

- [ ] Steviaglykosider
- [ ] Aspartam
- [ ] Askorbinsyra

61. För en patient med epilepsi, vad är det huvudsakliga syftet med behandlas med ketogen kost?

- [ ] Minska epileptiska anfall
- [ ] Förhindra hjärnskador
- [ ] Förhindra insulinresistens

62. Vilket av följande alternativ är en vanlig kostbehandling för ett spädbarn med medfött hjärtfel?

- [ ] Spädbarnsformula med låg energitäthet 0,7–1 kcal/ml
- [ ] Spädbarnsformula med justerad ratio av fett (n-3/n-6)
- [ ] Spädbarnsformula med högre energi och proteintäthet, 1–1,2 kcal/ml

DEL 2

63. Innan uppstart av parenteral nutrition rekommenderas kontroll av vissa blodprover. Vilket av nedan är ett exempel på sådant?

- [ ] P-Mg
- [ ] P-Zn
- [ ] P-Fe

64. Patienten har höga nivåer av LDL i blodet, vilket av nedanstående kostråd bör du ge för att på bästa sätt förbättra blodvärdena.

- [ ] Minska intaget av mättat fett, öka fiberintaget och nötter
- [ ] Öka det totala intaget av fett, undvik kolhydrater
- [ ] Minska den totala mängden fett, ät på regelbundna tider

65. Patienten har nyligen genomgått en gastric sleeve operation och ätit flytande kost men ska nu börja äta fast föda. Vilken av nedanstående menyförslag ger dietisten?

- [ ] Kokt potatis och panerad fisk med remouladsås, tomatsallad. Torkad fukt och vindruvor till dessert.
- [ ] Fiskgratäng med potatismos, kokta morötter och mixade bär till dessert.
- [ ] Pasta med köttfärssås, kokt broccoli. Vetebulle till dessert

66. För personer över 70 år, vilken BMI-nivå är ett fenotypiskt kriterie enligt GLIM?

- [ ] BMI >20
- [ ] BMI <22
- [ ] BMI <25

DEL 2

67. Vid kostrådgivning till en äldre person med xerostomi, vad av följande är lämpligt att rekommendera?

- [ ] Salta torra kex
- [ ] Mjuk och fuktig mat
- [ ] Kryddstark mat

68. Av vilken anledning kan personer med Parkinsons sjukdom rekommenderas att inta L-dopa cirka 30 minuter innan måltid?

- [ ] För att reducera läkemedlets negativa inverkan på matens smak
- [ ] För att hindra hyperglykemi
- [ ] För att undvika interaktion med aminosyror i maten

69. Vad av nedanstående kan du som dietist anta att följande patient lider av?
Kvinna, 68 år, diagnos: Multipel Skleros sedan 15 år tillbaka.
Patienten beskriver sig ha problem med rosslig röst och aspiration vid måltid.

- [ ] Dysfasi
- [ ] Apraxi
- [ ] Dysfagi

70. Efter en stroke kan hemianopsi bli ett problem för patienten. Hur kan detta påvekar en måltidssituation?

- [ ] Risk för att patienten inte ser hela måltiden
- [ ] Patienten har svårt för att sitta stilla under en hel måltid
- [ ] Patienten kan ha svårt för att hålla sig vaken en hel måltid

DEL 2

71. Vilken konsistens enligt IDDSI beskrivs nedan?
Kan skopas eller formas på en tallrik
Kan ätas med gaffel eller sked
Små synbara klumpar enkla att mosa med tunga

- [ ] Trögflytande
- [ ] Grovmalen och saftig
- [ ] Timbal/puré

72. Patient man 48 år, diagnos HIV/aids. Vilken punkt beskriver bäst vad patienten bör uppmärksammas på kring sin kosthållning?

- [ ] Patienten har nedsatt immunförsvar och bör vara extra uppmärksam på livsmedelshygien. Till exempel ska all mat som ska serveras varm upphettas till 70 grader Celsius för att undvika listerios.
- [ ] Patienten har ett minskat energibehov och bör uppmärksammas på att minska intaget av energitäta livsmedel.
- [ ] Patienten har ökat behov av antioxidanter och bör därför uppmanas att öka sitt intag av frukt och grönsaker för att säkerställa att behovet täcks.

73. Vilket av nedanstående påstående bör dietisten främst prioritera vid kostbehandling av patienten med KOL?

- [ ] Uppmuntra patienten med obesitas att gå ner i vikt
- [ ] Uppmuntra patienten att välja näringsrik och energilåga livsmedel
- [ ] Uppmuntra patienten att välja energitäta livsmedel som är enkla att förbereda

74. Vilket proteinbehov bedöms patienter med KOL ha?

- [ ] 1 gram/kg kroppsvikt
- [ ] 1,2–1,5 gram/kg kroppsvikt
- [ ] 0,6–0,8 gram/kg kroppsvikt

DEL 2

75. Patienten har genomgått kemoterapeutisk behandling för sin cancersjukdom. Initialt upplevde patienten att allt kändes bra men två dagar efter behandlingen har patienten fått stora besvär av illamående och kräkning. Patienten får läkemedel för att mildra symtomen. Vilken av nedanstående punkter gällande kostråd ska dietisten föreslå för att stödja patienten i dennes situation?

- [ ] Uppmuntrar patienten att välja sina favoriträtter för att förhoppningsvis få i sig någonting även om det blir begränsad mängd.
- [ ] Uppmanar patienten att stå ut, att allt blir bättre snart. Säger att det gör inget om det blir några dagar utan mat, huvudsaken är att behandlingen fungerar.
- [ ] Uppmuntrar patienten till att inta flera små frekventa mål per dag, välja kall mat som inte har någon stark doft.

76. Patienter med neutropeni har ökad risk för infektioner och kan därför vara hjälpt av kostråd i relation till säker mat. Vilket av kostråden nedan kännetecknar kostråd vid säker mat?

- [ ] Undvik konsumtion av animalier
- [ ] Tillaga, kyl och värm mat till korrekt temperatur
- [ ] Undvik pastöriserad mjölk

77. Vilken av följande är ett kännetecken av de metabola förändringar som sker vid cancercachexi?

- [ ] Minskad proteinkatabolism
- [ ] Ökad lipolys
- [ ] Minskad glukoneogenes

78. TNM-systemet används för att klassificera olika tumörer. Vad står ”T” för?

- [ ] Tumörstorlek
- [ ] Sekundärtumör
- [ ] Spridning till lymfnoder

DEL 2

79. Personer med kronisk njursvikt som ej ännu påbörjat dialys och har ett adekvat energiintag kan vid GFR <25 rekommenderas proteinreducerad kost. Hur många gram protein per kilo kroppsvikt är då aktuell rekommendation?

- [ ] 0,4 g/kg kroppsvikt
- [ ] 0,6 g/kg kroppsvikt
- [ ] 0,8 g/kg kroppsvikt

80. Vad av följande bör reduceras vid hyperkalemi?

- [ ] Oliver
- [ ] Torkad frukt
- [ ] Majsolja

81. Vilken är första steget i kostbehandlingen som en patient som diagnosticerats med IBS bör rekommenderas

- [ ] Eliminera alla gluteninnehållande produkter
- [ ] Eliminera alla livsmedel som har högt innehåll av fermenterbara oligosackarider, laktos och sockeralkoholer
- [ ] Eliminera alla livsmedel med högt fettinnehåll

82. Vid vilket tillstånd kan en kolektomi vara en botande behandling för sjukdomen?

- [ ] Morbus Crohn
- [ ] Ulcerös kolit
- [ ] Levercirros

DEL 2

83. Vilket av följande är ett vanligt patologiskt kännetecken för Ulcerös kolit?

- [ ] Strikturer
- [ ] Fistlar
- [ ] Kontinuerlig inflammation

84. Vad är sant om probiotika?

- [ ] Kost eller kosttillskott med levande bakterier som kan gynna hälsan
- [ ] Hälsofrämjande kolhydrater i kosten som upptas långsamt eller är icke-nedbrytbara
- [ ] Kost eller kosttillskott med levande bakterier kombinerat med hälsofrämjande kolhydrater i kosten som upptas långsamt eller är icke-nedbrytbara

85. Vad av följande är en vanligt bidragande orsak till malnutrition vid leversjukdom?

- [ ] Tidig mättnad
- [ ] Mucosit
- [ ] Tremor

86. Vad stämmer gällande Icke-alkoholorsakad fettleversjukdom (NAFLD)?

- [ ] Är ofta kopplad till alkohol
- [ ] Är ofta kopplad till metabola syndromet
- [ ] Ingen kostbehandling rekommenderas

DEL 2

87. Vilken typ av kostbehandling är bäst lämpad för patienten?
Man, 47 år med kronisk pankreatit. BMI 19, Intag per os 1900 kcal. Patienten besväras av smärta, inte sällan i samband med måltid. Patienten har även steatorré.

- [ ] Ordinerar initialt en fettreducerad kost 80g/dag, med utrymme för ökning om kosten tolereras.
- [ ] Utforskar om patienten substitueras med pankreasenzym, hur medicineringen intas och compliance, sänker vid behov fettet i kosten
- [ ] Ordinerar sondnäring via nasogastrisk sond som täcker hela energibehovet

88. När bör patienten med akut pankreatit avrådas från oralt intag de närmsta 24 timmarna

- [ ] Vid smärta, kräkning, ileus
- [ ] Alltid i samband med ett skov
- [ ] Aldrig, det är viktigt att komma igång med oralt intag direkt

89. Vilket av nedanstående livsmedel kan motverka dålig lukt/gasbildning i avföringen för en person med kolostomi?

- [ ] Ägg
- [ ] Fisk
- [ ] Tranbärsjuice

90. Vid total gastrektomi minskar förmågan att absorbera ett specifikt vitamin. Vilket?

- [ ] Vitamin A
- [ ] Vitamin B12
- [ ] Vitamin K

DEL 2

91. Dumping är en komplikation som kan uppstå efter ventrikelkirurgi. Vilket av följande påståenden om dumping är korrekt?

- [ ] Dumping är vanligast efter gastric sleeve men förekommer också efter gastric bypass
- [ ] Orsaken till dumping är företrädelsevis högt sockerintag
- [ ] Tidig dumping uppstår 15–30 min efter intagen måltid

92. Tillväxthormon är ett hormon både kan verka anabolt och katabolt. För att verka anabolt krävs närvaro av ett annat hormon nämligen

- [ ] Kortisol
- [ ] Insulin
- [ ] Adrenalin

93. Du träffar en patient som minskat 9 kg i vikt. Patientens nuvarande vikt är 77 kg. Vilken är patientens viktförlust i %?

- [ ] 8%
- [ ] 10%
- [ ] 12%

94. Du träffar en patient som är 35 år, väger 75 kg och är 162 cm lång. Hur bedömer du patientens BMI?

- [ ] Undervikt
- [ ] Normalvikt
- [ ] Övervikt

DEL 2

95. Du träffar en patient där målet för nutritionsbehandlingen är BMI 25. Patienter är 1,79 m lång.
Hur många kilo ska patienten väga för att nå önskat BMI?

- [ ] 80 kg
- [ ] 85 kg
- [ ] 90 kg

96. Vad av nedan är en indirekt metod för att skatta kroppslängd för en vuxen person?

- [ ] BMI
- [ ] Huvudomfång
- [ ] Armspännvidd

97. Vid vilken administreringsmetod för sondmatning tillförs matningen med matningsspruta?

- [ ] Bolusmatning
- [ ] Intermittent matning
- [ ] Kontinuerlig matning

98. Vid enteral nutrition finns olika administreringssätt för att tillföra sondnäringen. Vilket administreringssätt är det som beskrivs nedan?
Sondmatningen ges under 4 - 6 matningstillfällen under dagen med hjälp av pump eller gravitationsmatning.

- [ ] Kontinuerlig matning
- [ ] Intermittent matning
- [ ] Bolusmatning

DEL 2

99. Var mynnar sondspetsen för följande enterala infartsväg? *Nasoduodenal sond*

- [ ] Ventrikel
- [ ] Duodenum
- [ ] Jejunum

100. Var mynnar sondspetsen för följande enterala infartsväg? *PEG*

- [ ] Ventrikel
- [ ] Duodenum
- [ ] Jejunum

DEL 3

I denna del ska du läsa en vetenskaplig artikel *"Long-term secondary prevention of cardiovascular disease with a Mediterranean diet and a low-fat diet (CORDIOPREV): a randomised controlled trial"* och sedan svara på ett antal frågor kring den. Bilaga 4.

Det kan vara bra att läsa igenom frågorna innan du börjar läsa artikeln.

101. Vilket av nedanstående påståenden stämmer med den huvudsakliga bakgrunden till att man ville göra denna studie?

- [ ] De studier som gjort om Medelhavskost som sekundärprevention är för gamla
- [ ] Det har inte gjorts några bra större studier om Medelhavskost som sekundärprevention
- [ ] De studier som gjort om Medelhavskost som sekundärprevention har för få deltagare

102. Vad var studiens syfte?

- [ ] Att undersöka effektiviteten av en kombination av två hälsosamma kostinterventioner när det gäller sekundärprevention av hjärt-kärlsjukdomar
- [ ] Att undersöka effektiviteten av dietistbehandling när det gäller sekundärprevention av hjärt-kärlsjukdomar
- [ ] Att jämföra effektiviteten av två hälsosamma kostinterventioner när det gäller sekundärprevention av hjärt-kärlsjukdomar

103. Vad fick deltagarna för gratis mat under studien?

- [ ] En liter olivolja till ena gruppen och en hälsosam matkasse till den andra
- [ ] En liter olivolja och en hälsosam matkasse till alla deltagare
- [ ] Deltagarna fick välja mellan en liter olivolja och en hälsosam matkasse

DEL 3

104. Vilka deltagare var med i studien?

- [ ] Personer som förväntades leva längre än studien varade
- [ ] Personer som följde antingen en lågfettskost eller åt medelhavskost
- [ ] Personer med hjärt-kärlsjukdom

105. Vad innebar masking?

- [ ] Att bara dietisterna visste vilken diet deltagarna följde
- [ ] Att dietisterna inte visste vilken diet deltagarna följde förrän efteråt
- [ ] Att dietisterna inte talade om för deltagarna vilken diet de följde

106. Varför användes ingen kontrollgrupp som inte följde någon interventionskost?

- [ ] På grund av bristande resurser
- [ ] På grund av etiska orsaker
- [ ] På grund av att deltagarna ville ändra sin kost

107. Hur utvecklade sig deltagarnas ätande under studiens gång?

- [ ] Gruppen som ordinerats Medelhavskost ändrade sitt ätande i linje med sin interventionskost
- [ ] Gruppen som ordinerats lågfettskosten ändrade sitt ätande i linje med sin interventionskost
- [ ] Båda grupperna ändrade sitt ätande i linje med sin respektive interventionskost

DEL 3

108. Vad är korrekt avseende kardiovaskulära händelser för deltagarna under studiens gång?

- [ ] Inga kardiovaskulära händelser förekom
- [ ] Antalet kardiovaskulära händelser var lägre än väntat
- [ ] Antalet kardiovaskulära händelser var fler än i andra, liknande studier

109. Hur resonerar författarna kring generaliserbarheten i studien?

- [ ] Studien är inte generaliserbar till andra patientgrupper eller geografiska områden
- [ ] Studien kan med försiktighet generaliseras till andra patientgrupper och andra geografiska områden
- [ ] Studien är generaliserbar till andra patientgrupper men inte andra geografiska områden

110. Vilket av följande alternativ stämmer bäst överens med författarnas slutsats?

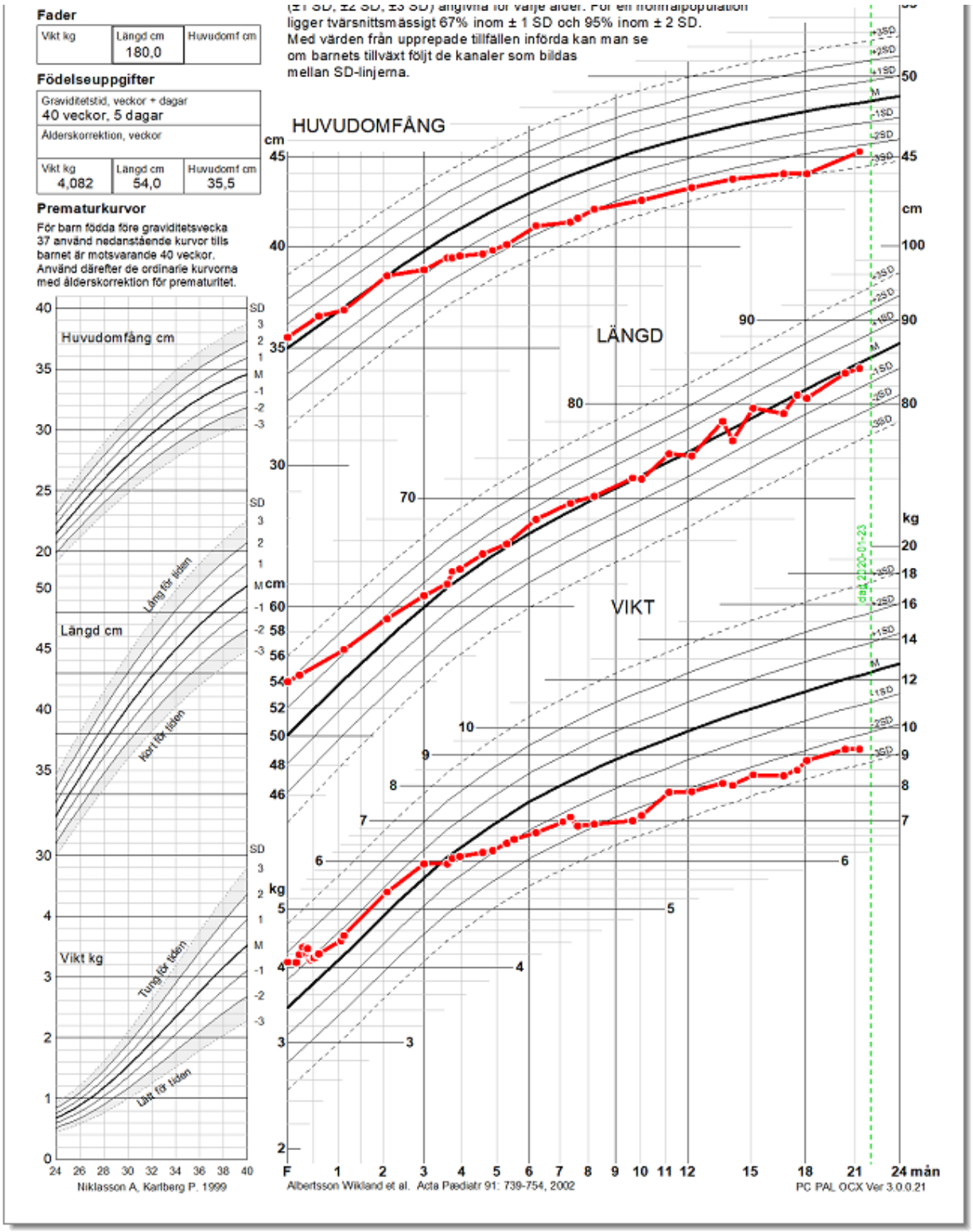
- [ ] Lågfettskosten och Medelhavskosten är lika effektiva för sekundärprevention av hjärt-kärlsjukdomar
- [ ] Lågfettskosten är mer effektiv för sekundärprevention av hjärt-kärlsjukdomar än Medelhavskosten
- [ ] Medelhavskosten är mer effektiv för sekundärprevention av hjärt-kärlsjukdomar än lågfettskosten

Table 4. Equations for resting energy expenditure (REE), adapted from Cloetens & Ellergård (2023). NNR6 2023 sid 339

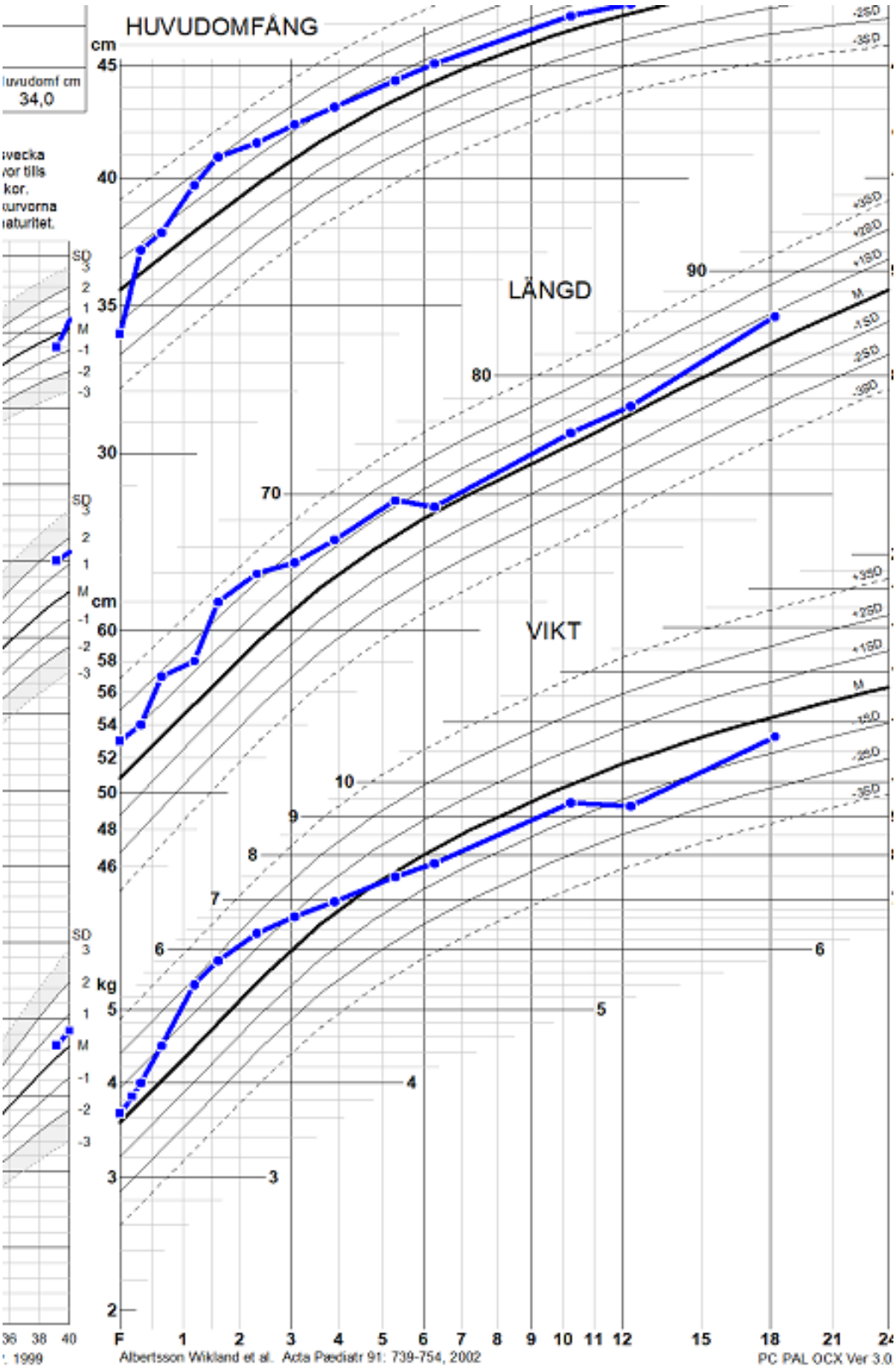
Bilaga 1.

Girls	
<3	0.127 W + 2.94 H – 1.20
3–10	0.0666 W + 0.878 H + 1.46
11–18	0.0393 W + 1.04 H + 1.93
Women	
19–30	0.0433 W + 2.57 H – 1.180
31–60	0.0342W + 2.10 H – 0.0486
61–70	0.0356 W + 1.76 H + 0.0448
>70	0.0356 W + 1.76 H + 0.0448
Boys	
<3	0.118 W + 3.59 H – 1.55
3–10	0.0632 W + 1.31 H +1.28
11–18	0.0651 W + 1.11 H + 1.25
Men	
19–30	0.0600 W + 1.31 H + 0.473
31–60	0.0476 W + 2.26 H – 0.574
61–70	0.0478 W 0+ 2.26 H – 1.070
>70	0.0478 W 0+ 2.26 H – 1.070

Bilaga 2.


Fader
Vikt kg
Längd cm
180,0
Huvudomf cm
Födelseuppgifter
Graviditetstid, veckor + dagar
40 veckor, 5 dagar
Ålderskorrektion, veckor
Vikt kg
4,082
Längd cm
54,0
Huvudomf cm
35,5
Prematurkurvor
För barn födda före graviditetsvecka 37 använd nedanstående kurvor tills barnet är motsvarande 40 veckor. Använd därefter de ordinarie kurvorna med ålderskorrektion för prematuritet.
Huvudomfång cm
Längd cm
Vikt kg
Lång för tiden
Kort för tiden
Tung för tiden
Lätt för tiden
Niklasson A, Karlberg P. 1999
ligger tvärsnittsmässigt 67% inom ± 1 SD och 95% inom ± 2 SD.
Med värden från upprepade tillfällen införda kan man se om barnets tillväxt följt de kanaler som bildas mellan SD-linjerna.
HUVUDOMFÅNG
LÄNGD
VIKT
Albertsson Wikland et al. Acta Paediatr 91: 739-754, 2002
PC PAL OCX Ver 3.0.0.21
24 mån

Bilaga 3.


HUVUDOMFÅNG
cm
LÄNGD
VIKT
kg
F 1 2 3 4 5 6 7 8 9 10 11 12 15 18 21 24
Albertsson Wikland et al. Acta Paediatr 91: 739-754, 2002
PC PAL OCX Ver 3.0

Long-term secondary prevention of cardiovascular disease with a Mediterranean diet and a low-fat diet (CORDIOPREV): a randomised controlled trial

Javier Delgado-Lista, Juan F Alcala-Diaz*, Jose D Torres-Peña, Gracia M Quintana-Navarro, Francisco Fuentes, Antonio Garcia-Rios, Ana M Ortiz-Morales, Ana I Gonzalez-Requero, Ana I Perez-Caballero, Elena M Yubero-Serrano, Oriol A Rangel-Zuñiga, Antonio Camargo, Fernando Rodriguez-Cantalejo, Fernando Lopez-Segura, Lina Badimon, Jose M Ordovas, Francisco Perez-Jimenez, Pablo Perez-Martinez†, Jose Lopez-Miranda†, for the CORDIOPREV Investigators‡*

Summary

Background **Mediterranean and low-fat diets are effective in the primary prevention of cardiovascular disease. We did a long-term randomised trial to compare the effects of these two diets in secondary prevention of cardiovascular disease.**

Methods **The CORDIOPREV study was a single-centre, randomised clinical trial done at the Reina Sofia University Hospital in Córdoba, Spain. Patients with established coronary heart disease (aged 20–75 years) were randomly assigned in a 1:1 ratio by the Andalusian School of Public Health to receive a Mediterranean diet or a low-fat diet intervention, with a follow-up of 7 years. Clinical investigators (physicians, investigators, and clinical endpoint committee members) were masked to treatment assignment; participants were not. A team of dietitians did the dietary interventions. The primary outcome (assessed by intention to treat) was a composite of major cardiovascular events, including myocardial infarction, revascularisation, ischaemic stroke, peripheral artery disease, and cardiovascular death. This study is registered with ClinicalTrials.gov, NCT00924937.**

Findings **From Oct 1, 2009, to Feb 28, 2012, a total of 1002 patients were enrolled, 500 (49·9%) in the low-fat diet group and 502 (50·1%) in the Mediterranean diet group. The mean age was 59·5 years (SD 8·7) and 827 (82·5%) of 1002 patients were men. The primary endpoint occurred in 198 participants: 87 in the Mediterranean diet group and 111 in the low-fat group (crude rate per 1000 person-years: 28·1 [95% CI 27·9–28·3] in the Mediterranean diet group *vs* 37·7 [37·5–37·9] in the low-fat group, log-rank p=0·039). Multivariable-adjusted hazard ratios (HRs) of the different models ranged from 0·719 (95% CI 0·541–0·957) to 0·753 (0·568–0·998) in favour of the Mediterranean diet. These effects were more evident in men, with primary endpoints occurring in 67 (16·2%) of 414 men in the Mediterranean diet group versus 94 (22·8%) of 413 men in the low-fat diet group (multiadjusted HR 0·669 [95% CI 0·489–0·915], log-rank p=0·013), than in 175 women for whom no difference was found between groups.**

Interpretation **In secondary prevention, the Mediterranean diet was superior to the low-fat diet in preventing major cardiovascular events. Our results are relevant to clinical practice, supporting the use of the Mediterranean diet in secondary prevention.**

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*Contributed equally as joint first authors

†Joint senior authors

‡Study group investigators are listed in the appendix

Lipids and Atherosclerosis Unit, Department of Internal Medicine, Hospital Universitario Reina Sofía, Córdoba, Spain (J Delgado-Lista MD, J F Alcala-Diaz MD, J D Torres-Peña MD, G M Quintana-Navarro PhD, F Fuentes MD, A Garcia-Rios MD, A M Ortiz-Morales MD, A I Gonzalez-Requero MD, A I Perez-Caballero MD, E M Yubero-Serrano PhD, O A Rangel-Zuñiga PhD, A Camargo PhD, F Lopez-Segura MD, Prof F Perez-Jimenez MD, Prof P Perez-Martinez MD, Prof J Lopez-Miranda MD); **Department of Medical and Surgical Sciences, Universidad de Córdoba, Córdoba, Spain** (J Delgado-Lista, J F Alcala-Diaz, F Fuentes, A Garcia-Rios, Prof F Perez-Jimenez, Prof P Perez-Martinez, Prof J Lopez-Miranda); **Maimonides Institute for Biomedical Research in Córdoba (IMIBIC), Córdoba, Spain** (J Delgado-Lista, J F Alcala-Diaz, J D Torres-Peña, G M Quintana-Navarro, F Fuentes, A Garcia-Rios, E M Yubero-Serrano, O A Rangel-Zuñiga, A Camargo, F Lopez-Segura, Prof F Perez-Jimenez, Prof P Perez-Martinez, Prof J Lopez-Miranda); **CIBER Fisiopatologia Obesidad y Nutricion (CIBEROBN), Instituto de Salud Carlos III, Madrid, Spain** (J Delgado-Lista, J F Alcala-Diaz, J D Torres-Peña,

Introduction

Besides drugs and invasive interventional measures (eg, revascularisation), lifestyle is a clear determinant of both incidence and recurrence of cardiovascular events. Among its components, diet is the most studied and supported factor.[1–10] The composition of the optimal diet for cardiovascular prevention has been evolving over the past decades. In the first part of the 2000s, reducing fat consumption was the standard approach in patients with cardiovascular disease. This approach was based on two main guidelines: the National Cholesterol Education Program II and the Adult Treatment Panel III guidelines.[11,12] Although the National Cholesterol Education Program II was stricter in fat reduction, the Adult Treatment Panel III emphasised the type of carbohydrates (eg, complex carbohydrates) used to replace saturated fats and correct fibre composition. However, the guideline did not raise the lower recommended limit for fats, keeping it to 25% (desirable limits are 25–35%). Therefore, a low-fat diet was the recommended option. A Mediterranean diet, characterised by a relatively high proportion of fruits, vegetables, legumes, and cereals, white meat and fish as the primary source of protein, and olive oil as the main source of fat, traditionally had been identified as a diet with a potential healthy composition. In the PREDIMED study, the Mediterranean diet has also proven effective in primary prevention in people at high risk of cardiovascular disease[13] compared with a control

F Fuentes, A Garcia-Rios, E M Yubero-Serrano, O A Rangel-Zuñiga, A Camargo, F Lopez-Segura, Prof F Perez-Jimenez, Prof P Perez-Martinez, Prof J Lopez-Miranda); **Biochemical Laboratory, Reina Sofia University Hospital, Córdoba, Spain** (F Rodriguez-Cantalejo MD); **Cardiovascular Program ICCC, Hospital de la Santa Creu i Sant Pau Research Institute, IIB-Sant Pau, Barcelona, Spain** (Prof L Badimon PhD); **CIBER-CV, Instituto de Salud Carlos III, Spain** (Prof L Badimon); **Cardiovascular Research Chair, UAB, Barcelona, Spain** (Prof L Badimon); **Nutrition and Genomics Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging, Tufts University, Boston, MA, USA** (Prof J M Ordovas PhD); **IMDEA Food Institute, Madrid, Spain** (Prof J M Ordovas)

Correspondence to: Prof Jose Lopez-Miranda or Javier Delgado-Lista, Lipids and Atherosclerosis Research Unit, Department of Internal Medicine, Hospital Universitario Reina Sofía, 14004 Córdoba, Spain **jlopezmir@uco.es, md1delij@uco.es**

See **Online** for appendix

Research in context

Evidence before this study

Evidence from clinical trials of the effect of a Mediterranean diet in secondary prevention of cardiovascular disease is scarce. Two reviews highlight the need for clinical data from clinical trials. A Cochrane Library report evaluated current knowledge about the effects of the Mediterranean diet on primary and secondary prevention. The authors conclude that there is a paucity of evidence for secondary prevention and that the ongoing studies might provide more certainty in the future. In that report, accumulated data were available from 605 patients on the Mediterranean diet for 4 years versus usual care, and 101 patients on the Mediterranean diet for 2 years versus an active comparator, compared with the 1002 patients on the Mediterranean diet versus low-fat diet for 7 years in our CORDIOPREV study. A 2019 critical review by Martinez-Gonzalez and colleagues analysing the effect of the Mediterranean diet highlights the need for new data on secondary prevention, because the only two significant existing studies were either too short (de Lorgeril and colleagues, 1999) or they presented some concerns (Singh and colleagues, 2002). Although clinical guidelines recommend the Mediterranean diet for secondary prevention, there have been no clinical trials in the past 20 years to support this recommendation.

Added value of this study

The CORDIOPREV study is the only trial in the past 23 years (excluding one subjected to an expression of concern) evaluating the effect of the Mediterranean diet versus any other active comparator in the secondary prevention of cardiovascular disease. This implies that the effect of the Mediterranean diet in the set of current treatment guidelines has not been tested until the CORDIOPREV study. The results of our study provide evidence that the Mediterranean diet is better than the low-fat diet in preventing cardiovascular recurrence. Our study is the most extensive study on secondary prevention with a Mediterranean diet, has the longest follow-up, and had more reported events.

Implications of all the available evidence

This study is a hallmark for the effect of the Mediterranean diet on secondary prevention of cardiovascular disease and can be used to change clinical guidelines on diet recommendations and follow-up of patients with coronary heart disease.

diet (which had advice to reduce dietary fat). Active intervention by dietitians was done to equalise the intensity of the intervention between groups.[13] However, despite epidemiological and mechanistic studies showing similar results,[14–21] no evidence from large-scale, long-term clinical trials exists on the efficacy of the Mediterranean diet on secondary cardiovascular prevention, especially when compared with another active group. The CORDIOPREV study, a long-term, large-scale clinical trial aimed to compare the efficacy of two healthy dietary interventions (a low-fat diet and a Mediterranean diet) in secondary cardiovascular prevention.

Methods

Study design

The CORDIOPREV study was a single centre, randomised, dietary intervention clinical trial in patients with coronary heart disease developed at Reina Sofia University Hospital in Córdoba, Spain. Details of the trial design are provided elsewhere.[22] Extra-virgin olive oil was provided free of charge to the participants in the Mediterranean diet group (1 L per week per household). Healthy food bag packs, rich in complex carbohydrates, were provided, free of charge, to the participants in the low-fat diet group, with similar commercial value. The ethics approval and study protocol can be found on the IMIBIC website.

For the **ethics approval** see https://www.imibic.org/documents/cordioprevethic.pdf

For the **study protocol** see https://www.imibic.org/documents/cordioprevprotocol.pdf

Participants

The inclusion and exclusion criteria have been previously published.[22] Eligible patients included men and women aged 20–75 years who had established coronary heart disease, were free of clinical events related to coronary heart disease in the previous 6 months, were able to follow a long-term dietary intervention, and had no severe illnesses or an expected life expectancy lower than the length of the study. The upper age limit was set on the basis of the life expectancy at the conception of the trial (2007) and according to the usual practice in contemporary long-term cardiovascular studies. Patients gave their written informed consent to participate in the study. The three criteria for established coronary heart disease in the CORDIOPREV study were: acute myocardial infarction, hospitalisation for unstable angina, or chronic high-risk ischaemic heart disease (patients with hospitalisation for a coronary event or stable angina with an image diagnostic test showing an epicardial vessel greater than 2·5 mm in diameter with stenosis of more than 50%). More details on these criteria have been published.[22]

Randomisation and masking

The process of randomisation (1:1) to the low-fat diet or the Mediterranean diet was done by the Andalusian School of Public Health (Granada, Spain), with fixed randomisation stratified in blocks, based on sex, age, and the existence of previous acute myocardial infarction (appendix).

Randomisation was blinded to dietitians, physicians, or any other personnel in the CORDIOPREV team. The procedure for assigning a diet was as follows: when there was a candidate for randomisation, the study dietitians telephoned the person in charge of the study in the Andalusian School of Public Health who then communicated the assigned diet to the dietitian. The CORDIOPREV team, including dietitians, did not know if randomisation

was done by blocks or other methods. Individual allocation documents were recorded in both institutions, and then by weekly telephone calls to ensure the correct allocations were done. The only physician auditing the randomisation was the clinical coordinator, who, together with the head of the randomisation team at the Andalusian School of Public Health, reviewed the allocations. The clinical coordinator did not make clinical visits.

Regarding masking, dietitians were the only members of the intervention team who knew the diet of each patient. Physicians and other members of the CORDIOPREV team who carried out clinical follow-up and analysis of the patients were unaware of the diets. Participants were instructed not to comment to the physicians on anything related to diet. This was a crucial point of our study, and even separate rooms for the visits related to diet or clinical follow-up were used. The clinical endpoint committee was also unaware of the diets consumed by the patients.

Procedures

The intervention had a median follow-up of 7 years. Dietary and clinical monitoring was carried out by dietitians, internists, and cardiologists. The dietary models were (1) the Mediterranean diet, comprising a minimum of 35% of the calories as fat (22% monounsaturated fatty acids, 6% polyunsaturated fatty acids, and <10% saturated fat), 15% proteins, and a maximum of 50% carbohydrates, and (2) the low-fat, high complex carbohydrates diet, comprising less than 30% of total fat (<10% saturated fat, 12–14% monounsaturated fatty acids, and 6–8% polyunsaturated fatty acids), 15% protein, and a minimum of 55% carbohydrates. In both diets, the cholesterol content was adjusted to less than 300 mg per day.[22] Dietary adherence was assessed with the 14-point Mediterranean Diet Adherence Screener and 9-point low-fat diet adherence.[13] No energy restriction was implemented and the study team explicitly did not promote physical activity. The dietary intervention in the CORDIOPREV study included individual face-to-face visits every 6 months, group sessions every 3 months, and telephone calls every 2 months, all of which aimed at guaranteeing frequent contact between the patients and dietitians (at least 12 interactions per year). During the study, the following interventions were done: regular contacts, group sessions, monitoring of adherence, goal setting, social support, and the provision of foods. Based on previous studies,[23,24] we consider that the intervention was of high intensity. Table 1 shows a summary of dietary recommendations to the patients in the two intervention groups. Further details on the dietary intervention, along with the results of the adherence of the dietary models during the first 7 years, are in the appendix (pp 7–17, 22–30).

Outcomes

The primary outcome of the CORDIOPREV study was a composite of major cardiovascular events, including myocardial infarction, revascularisation, ischaemic stroke, documented peripheral artery disease, and cardiovascular death, for 7 years. Prespecified secondary outcomes are in the appendix (pp 18–20).

	Mediterranean diet group	Low-fat diet group
Oil (including the oil used for cooking, dressing, and meals consumed outside the home)	Four or more tablespoons of extra virgin olive oil per day (40–60 g per day)	Less than two tablespoons of vegetable oils (eg, sunflower oil or regular olive oil) per day (20–30 g per day)
Fruit	Three or more servings of fresh fruit and natural fruit juices per day	Three or more servings of fresh, frozen, canned, or dried fruits per day
Vegetables	Two or more servings per day (at least one serving raw or as a salad)	Two or more servings per day (fresh, frozen, or canned, without added fat, sauce, or salt)
Grains and potatoes	Six servings of preferably whole grains per day	Six to 11 servings of grains (preferably whole grains), potatoes, and legumes per day
Legumes	Three or more servings per week	Six to 11 servings of grains (preferably whole grains), potatoes, and legumes per day
Dairy	Two servings per day	Two to three servings of low-fat or fat-free dairy products per day
Tree nuts	Three or more servings of raw, non-roasted, or fried nuts per week	Occasional consumption (one serving or less) of raw, non-roasted, or fried nuts per week
Fish and seafood	Three or more servings of especially fatty fish per week	Choose lean fish; limit fatty fish and seafood canned in oil to one serving or fewer per week
White meat	Consume white meat (eg, chicken, turkey, or rabbit) instead of red meat; remove skin and visible fat	Choose skinless poultry and lean cuts (eg, loin or round)
Red or processed meats	Less than one serving per week	One serving or fewer per week
Eggs	Two to four units per week	Two or fewer egg yolks per week
Commercial bakery products, sweets, and pastries	One serving or fewer per week	One serving or fewer per week
Butter and margarine	Not allowed	One serving or fewer per week
Wine	Optional consumption, only in case of a habitual wine drinker (one glass per day for women and two glasses per day for men)	Not allowed
Sweet or carbonated beverages	Less than one drink per day	Less than one drink per day
Culinary techniques	Use of sofrito (a homemade sauce with garlic, onion, aromatic herbs, and tomato slow cooked in olive oil) two or more times a week	Use low-fat cooking methods (eg, broiling, grilling, roasting, baking, microwaving, and poaching); avoid frying and use of sofrito; remove the visible fat before cooking

Table 1: **Summary of dietary recommendations to the patients in the two intervention groups of the CORDIOPREV study**

Statistical analysis

The sample size and power calculation were calculated on the following assumptions: an incidence rate in the low-fat group of 4 events per 100 person-years that would amount to 24·9% of absolute cumulative incidence after 7 years, a hazard ratio (HR) of 0·7, and statistical power of 80%, with two-tailed α=0·05. Under these assumptions, the required sample size was 491 patients in each of the two groups. This sample size was

	All patients (n=1002)	Mediterranean diet group (n=502)	Low-fat diet group (n=500)
Age, years	59·5 (0·2)	59·7 (0·4)	59·5 (0·4)
Sex			
Male	827 (82·5%)	414 (82·5%)	413 (82·6%)
Female	175 (17·5%)	88 (17·5%)	87 (17·4%)
Metabolic syndrome	581 (58·0%)	279 (55·6%)	302 (60·4%)
Systolic blood pressure, mm Hg	138·8 (0·6)	138·5 (0·9)	139·0 (0·9)
Diastolic blood pressure, mm Hg	77·2 (0·3)	77·2 (0·5)	77·3 (0·5)
Weight, kg	85·1 (0·4)	84·9 (0·6)	85·4 (0·7)
Height, m	1·65 (0·0)	1·65 (0·0)	1·65 (0·0)
Waist circumference, cm	105·1 (0·3)	104·9 (0·5)	105·4 (0·5)
Body-mass index, kg/m²	31·1 (0·1)	31·0 (0·1)	31·2 (0·2)
Total cholesterol, mg/dL	159·0 (1·0)	159·1 (1·5)	159·0 (1·3)
HDL cholesterol, mg/dL	42·2 (0·3)	42·3 (0·5)	42·1 (0·5)
LDL cholesterol, mg/dL	88·5 (0·8)	88·9 (1·2)	88·2 (1·1)
Apolipoprotein A1, mg/dL	129·6 (0·7)	129·7 (1·0)	129·5 (0·9)
Apolipoprotein B, mg/dL	73·6 (0·5)	73·6 (0·8)	73·7 (0·8)
Triglycerides, mg/dL	135·4 (2·2)	134·8 (3·1)	136·0 (3·2)
Fasting plasma glucose, mg/dL	113·7 (1·2)	114·7 (1·8)	112·8 (1·6)
Family history of premature coronary artery disease	149 (14·9%)	75 (14·9%)	74 (14·8%)
Family history of diabetes	468 (46·7%)	229 (45·6%)	239 (47·8%)
Diabetes*	540 (53·9%)	256 (51·0%)	284 (56·8%)
Hypertension	683 (68·2%)	346 (68·9%)	337 (67·4%)
Normal systolic function (left ventricular ejection fraction ≥50%)	951 (94·9%)	473 (94·3%)	478 (95·6%)
History of myocardial infarction	620 (61·9%)	312 (62·2%)	308 (61·6%)

(Table 2 continues in next column)

	All patients (n=1002)	Mediterranean diet group (n=502)	Low-fat diet group (n=500)
(Continued from previous column)			
History of coronary artery bypass grafting	32 (3·2%)	19 (3·8%)	13 (2·6%)
History of percutaneous coronary intervention	914 (91·2%)	456 (90·8%)	458 (91·6%)
Current smoker	95 (9·7%)	43 (8·7%)	52 (10·7%)
Former smoker	635 (64·6%)	317 (63·8%)	318 (65·4%)
History of stroke or transient ischaemic attack	51 (5·1%)	26 (5·2%)	25 (5·0%)
History of peripheral vascular disease	29 (2·9%)	15 (3·0%)	14 (2·8%)
History of previous malignancy	26 (2·6%)	18 (3·6%)	8 (1·6%)
Baseline medication			
Antiplatelets or anticoagulants	963 (98·2%)	479 (98·4%)	484 (98·0%)
Statins	858 (86·6%)	426 (84·9%)	432 (86·4%)
Other lipid-lowering drugs	231 (23·1%)	123 (24·5%)	108 (21·6%)
Angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers	834 (83·2%)	414 (82·5%)	420 (84·0%)
β-blockers	803 (80·1%)	404 (80·5%)	399 (79·8%)
Calcium antagonist	295 (29·4%)	145 (28·9%)	150 (30·0%)
Diuretics	526 (52·5%)	261 (52·0%)	265 (53·0%)
Insulin	114 (11·4%)	58 (11·6%)	56 (11·2%)
Oral antidiabetics	329 (32·8%)	160 (31·9%)	169 (33·8%)

Data are mean (SE) or n (%). We used unpaired *t* tests for quantitative variables and χ^2 for categorical variables. This table was adapted from Delgado-Lista et al[22] with permission from the American Heart Journal. *Including patients who self-reported as previously diagnosed with diabetes and those who met the American Diabetes Association diagnostic criteria of HbA_{1c} concentrations of 6·5% or more, fasting blood glucose of 126 mg/dL or more, or a 2 h blood glucose of 200 mg/dL or more after 75 g of oral glucose overload done at baseline.

Table 2: **Baseline characteristics**

recalculated over the original, based on a reduction of criteria applying as primary endpoint components to hardpoints and increasing the follow-up to 7 years, which was decided upon external advisory board suggestion in the third year, and according to the prespecified sample size revision made in the study protocol. Subsequently, two interim analyses were added to the two planned initially, and they were established for years 3, 4, 5, and 6 (O'Brien-Fleming, prespecified p values for the anticipated end of the study were 0·001, 0·004, 0·019, and 0·043, respectively). Power curves for the original assumptions of the number of events are in the appendix (p 20).

The analysis was done under the principle of intention-to-treat. All patients were included in the primary analysis. Treatment of patients who abandoned the dietary intervention was as follows: if the patient allowed follow-up by electronic health records, we treated the data as patients included in the study, scouting data from electronic health records until their seventh year from recruitment. If the patient denied permission to be followed up, we analysed the data until abandonment of the dietary intervention and censored the patient at that moment. Statistical comparisons were done using two-sided significance tests. The primary statistical comparison was made by log-rank analysis with Kaplan-Meier survival estimates and several Cox proportional hazards models were adjusted for the following covariates: model 1: age and sex; model 2: age, sex, family history of early coronary heart disease, and smoking; model 3: age, sex, family history of early cardiovascular disease, smoking, body-mass index (BMI), LDL cholesterol, diabetes, and hypertension; model 4: age,

sex, hypertension, LDL cholesterol (<100 mg/dL), BMI, smoking, statins (intensity), and diabetes; model 5: model 2 plus pharmacological treatments at baseline; model 6: model 4 plus changes in weight and physical activity during follow-up; and model 7: all covariates used in the different models and randomisation order. The significance level for all the analyses was α=0·05. Sensitivity analyses were done for these cases: primary endpoint excluding cases in the first month; cases in the first 6 months; patients with a mean adherence greater than 80% during the study; patients with an extended composite of a cardiovascular endpoint; and extended composite of heart events and randomisation order. SPSS (version 25.0) and R statistical software (version 3.6.1) were used for the statistical study. This study is registered with ClinicalTrials.gov, NCT00924937.

Role of the funding source
The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results
From Oct 1, 2009, to Feb 28, 2012, 1850 patients were screened for eligibility and 1002 were included in the CORDIOPREV study. 500 (49·9%) of 1002 patients were assigned to the low-fat diet group and 502 (50·1%) to the Mediterranean diet group.[22] The population was mostly men (82·5%), and the average age was 59·5 years (table 2). By the end of the study, on July 1, 2018, a total of 132 (13·8%) of 1002 participants had abandoned the dietary intervention (figure 1). These cases were higher in the low-fat group (86 [17·2%]) than in the Mediterranean diet group (46 [9·2%]; p=0·0002; appendix p 21). 112 (84·8%) of 132 participants who left the dietary intervention were followed up by electronic health records or phone calls after giving their permission. 14 (2·8%) of 500 participants in the low-fat diet and six (1·2%) of 502 in the Mediterranean diet abandoned the dietary intervention and denied their permission to be followed up by electronic health records or phone calls, and therefore were censored at that point. The median follow-up of the whole population of the study (n=1002) was 2557 days (IQR 173).

Baseline adherence of the whole population to the Mediterranean diet was 8·78 on the 0–14 scale[25,26] (14 being the best possible adherence rate for the Mediterranean scale) and 3·81 on the 0–9 scale for the low-fat diet (9 being the best possible adherence rate for the low-fat diet score).[22] Participants adhered to the group they were randomly assigned to and maintained this adherence during the study. Most of the dietary change happened during the first year, with increases of 1·99 points in the Mediterranean diet group and 2·53 points in the low-fat group.[27] Data for all 7 years are in appendix (pp 22–23).

At the end of the study, patients in the Mediterranean diet group had significantly increased their intake of total fat (from 37·4% to 40·5% of the total energy intake), monounsaturated fatty acids (from 18·4% to 21·4% of the total energy intake), and polyunsaturated fatty acids (from 6·4% to 7·4% of the total energy intake), which was related to higher intakes of extra-virgin olive oil (from 31 g to 48 g per day), nuts (from 2·1 to 3·9 servings per week), and oily fish (from 2·8 to 3·2 servings per week) in comparison with those in the low-fat diet group. In addition, the Mediterranean diet group reduced their consumption of total carbohydrates (from 41·4% to 39·4% of the total energy intake) and saturated fatty acids (from 9·0% to 7·9% of the total energy intake). As expected, the low-fat diet group showed an increased intake of carbohydrates (from 41·7% to 45·5% of the total energy intake), mainly complex carbohydrates, and a decreased consumption of total fat (from 36·7% to 32·1% of the total energy intake), monounsaturated fatty acids (from 17·9% to 15·1% of the total energy intake), and saturated fatty acids (from 8·9% to 7·1% of the total energy intake). Both the Mediterranean and the low-fat diet groups increased their fibre intake (by 2·3 g per 1000 kcal *vs* 3·2 g per 1000 kcal) due to a higher intake of vegetables, fruits, and legumes. In addition, decreases in the intake of red or processed meats, sweet or carbonated beverages, and fat spreads were observed in the two intervention groups (appendix pp 24–31).

The different pre-established interim analyses did not reach the threshold to stop the study. In the seventh year,

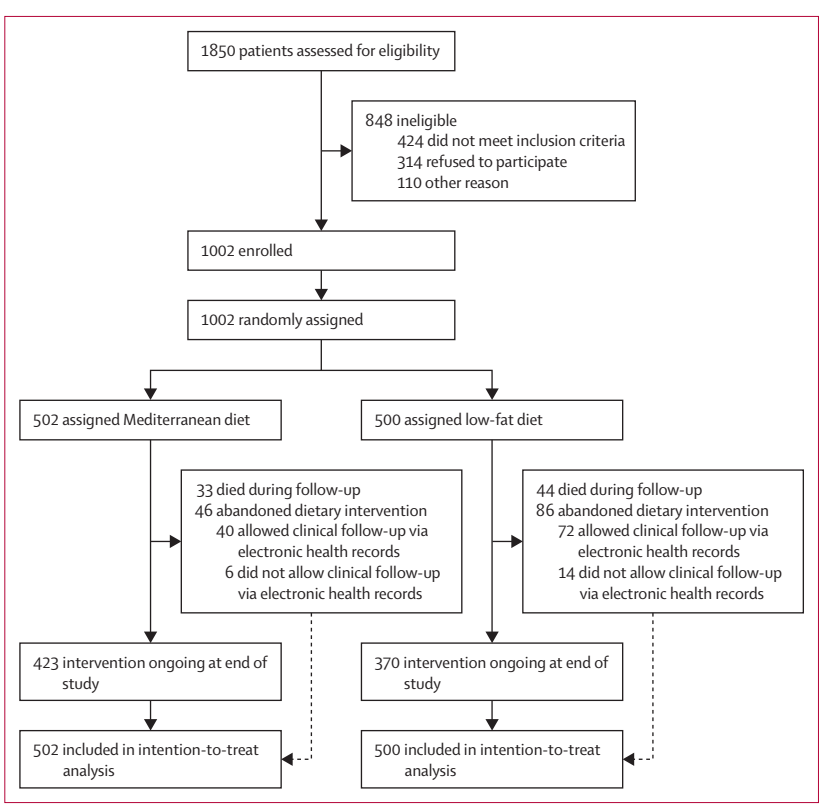

Figure 1: **Trial profile**

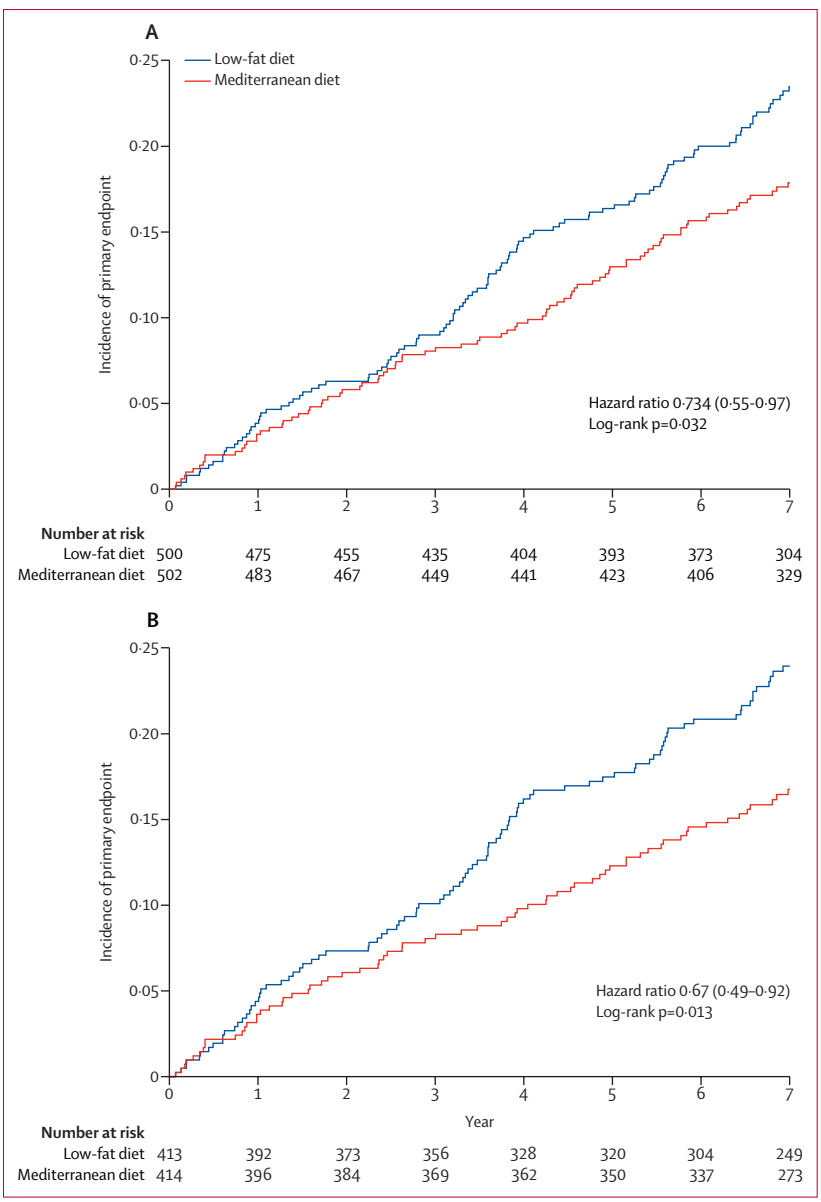

Figure 2: **Kaplan-Meier estimates of the incidence of the composite primary endpoints of myocardial infarction, revascularisation, ischaemic stroke, documented peripheral artery disease, and cardiovascular death events**
(A) Total study population of the CORDIOPREV study. (B) Male population (827 [82·5%] of 1002) of the CORDIOPREV study. Hazard ratios and confidence intervals are from the multivariable-adjusted Cox model (adjusted for diet, age, family history of coronary disease, and smoking).

a decision was made to stop the study after registering a total of 198 primary-outcome events: 87 (17·3%) in the Mediterranean diet group and 111 (22·2%) in the low-fat group. The unadjusted HR was 0·745 (95% CI 0·563–0·986). The crude rate per 1000 person-years was 28·1 (95% CI 27·9–28·3) for the Mediterranean diet group and 37·7 (37·5–37·9) for the low-fat diet group (log-rank p=0·039; figure 2A).

Table 3 shows the results of the multivariable adjusted Cox HRs. In all models, the Mediterranean diet was superior to the low-fat diet. HRs for the primary endpoint ranged from 0·719 to 0·753 in the different models. When evaluating the different components of the composite primary outcome, we did not find any significant statistical difference between diets. The specific number of events for each component was: non-fatal myocardial infarction (Mediterranean diet 19, low-fat 24, p=0·366); cardiovascular death (Mediterranean diet 11, low-fat 20, p=0·120); revascularisation (Mediterranean diet 64, low-fat 77, p=0·171); ischaemic stroke (Mediterranean diet 8, low-fat 15, p=0·123); and peripheral artery disease (Mediterranean diet 11, low-fat 17, p=0·223; appendix p 32).

We did different sensitivity analyses to test cases at the beginning of the study (cases in the first month and the first 6 months), with results similar to those of the primary analysis. In people with a high dietary adherence during the study (mean adherence ≥80% during the study, excluding time 0), the Mediterranean diet was superior to the low-fat diet (HR 0·602, 95% CI 0·385–0·941, p=0·026). In the evaluation of the extended composite of heart events (ie, myocardial infarction, unstable angina, cardiac arrest, and heart failure), the Mediterranean diet was superior to the low-fat diet (HR 0·745, 95% CI 0·580–0·956, p=0·021; appendix pp 33–34).

When evaluating patient subgroups, the Mediterranean diet was superior to the low-fat diet in patients without a family history of coronary heart disease, in those without hypertension at baseline, in those younger than age 70 years at study entry, and those with an LDL cholesterol lower than 100 mg/dL (appendix p 38). Lipid and glucose parameters did not change significantly during the study (appendix p 35). Three sensitivity analyses were done regarding missing data analysis, not varying for main results (appendix p 36).

In the male population (n=827), a total of 161 primary endpoints occurred: 67 (16·2%) in the Mediterranean diet group and 94 (22·8%) in the low-fat diet group. The log-rank p value for the primary endpoint was 0·013 favouring the Mediterranean diet group (figure 2b). Cox-regression multiadjusted HRs for the primary endpoint in the different adjusted models ranked from 0·669 (95% CI 0·489–0·915, p=0·012) to 0·684 (0·500–0·936, p=0·018) for the Mediterranean diet group versus the low-fat diet group (appendix p 39). We did not find statistical differences in women (appendix p 38). The use of medication and anthropometric measurements during the study are in the appendix (p 40).

Discussion

In our study, evaluating the effects of a comprehensive, high-intensity dietary intervention with a Mediterranean diet or a low-fat diet over 7 years of follow-up in 1002 patients with coronary heart disease, the Mediterranean diet was superior to the low-fat diet in preventing a major cardiovascular event, with a decrease of HR of 26%. In men, the Mediterranean diet showed an

even higher superiority than the low-fat diet, with a nearly 33% reduction in major cardiovascular events. The Mediterranean diet also showed higher efficacy in the total cohort (men and woman) without a family history of coronary heart disease, in participants with an LDL less than 100 mg/dL at baseline, in patients younger than age 70 years at study entry, and those with a dietary adherence of more than 80% to the assigned diet throughout the study.

The CORDIOPREV study was a secondary prevention trial. Therefore, the use of a control diet was not ethically appropriate. Consequently, the experimental approach investigated two high-intensity dietary interventions with equal intensity in both groups. All patients received comprehensive, tailored, and continuous dietary support, regardless of the study group. As our results show, the intervention effectively changed the dietary habits for both the Mediterranean and the low-fat diet groups resulting in significant dietary changes towards the assigned diet. Participants in the low-fat diet group managed to reduce their total fat intake from 36·7% to 32·1% (mean decrease of 12·5% of fat consumption), which was higher than that reported in similar intervention studies.[13] Because both intervention groups were submitted to a high-intensity dietary intervention with participants reaching and maintaining a high adherence to the two healthy dietary patterns during the study, on top of the optimal medical treatment, we had a lower-than-expected rate of cardiovascular events in our trial. Our results were collected in the setting of a controlled environment, where adherence to diets, meetings with dietitians, and positive reinforcement might have contributed significantly to our results. Therefore, our results should be extrapolated with caution to other environments.

Our study did not find differences in glucose or main lipids between diets at the beginning or at the end of the dietary intervention. A Mediterranean diet has been associated with an improvement in lipids profile and glucose when compared with diets rich in saturated fats. However, this improvement has not been so uniform when compared with low-fat diets, primarily when an adequate fibre intake has been provided and complex carbohydrates were the main source of energy. Also, the fact that these patients were in secondary prevention and mostly taking hypolipidaemic drugs (mostly statins) might have influenced the differential effects on lipids and glucose of both groups of dietary intervention.

To our knowledge, this study is the most extensive to date evaluating the effects of a Mediterranean diet and a low-fat diet in the prevention of recurrent cardiovascular events in the context of two high-intensity dietary interventions. It is important to highlight that the Mediterranean diet used in the Lyon Diet Heart Study, for example, was supplemented with canola oil, which is not a traditional source of fat in the Mediterranean region. Moreover, the comparator was a "prudent Western-type diet" and not a healthy comparator.[28] A 2019 Cochrane report evaluated current knowledge about the effects of the Mediterranean diet on primary and secondary prevention.[29] The authors concluded that, "There is a paucity of evidence for secondary prevention. The ongoing studies might provide more certainty in the future".[29] Accumulated data included in the Cochrane report were from 605 patients at 4 years for the Mediterranean diet versus usual care, and 101 patients during 2 years for the Mediterranean diet versus an active group, compared with 1002 patients from the CORDIOPREV study on the Mediterranean diet versus the low-fat diet for 7 years. Another review analysing the effect of the Mediterranean diet[30] highlights the need for new data on secondary prevention, as the only two significant existing studies were either too short[28] or show some concerns.[31]

In our study, the primary endpoint occurred in 19·8% of the population, and death occurred in less than 8% of participants. In comparison, a retrospective study evaluating the cardiovascular prognosis of coronary patients in our setting, and in the same timeframe of the CORDIOPREV study, reported a 20% mortality after 6 years of follow-up, which was more than double the percentage of deaths in the CORDIOPREV study.[32] Similarly, other large studies evaluating the efficacy of different drugs in this type of patient reported higher major cardiovascular event rates than our population, both in the active and the placebo groups of these studies.[33,34] The fact that primary endpoint rates were lower than

	Mediterranean diet (n=502)	Low-fat diet (n=500)	p value
Unadjusted	0·745 (0·563–0·986)	1 (ref)	0·040
Multivariable adjusted for age and sex	0·738 (0·558–0·978)	1 (ref)	0·034
Multivariable adjusted for age, sex, family history of early coronary heart disease, and smoking	0·734 (0·555–0·974)	1 (ref)	0·032
Multivariable adjusted for age, sex, family history of early cardiovascular disease, smoking, BMI, LDL cholesterol, diabetes, and hypertension	0·753 (0·568–0·998)	1 (ref)	0·049
Multivariable adjusted for age, sex, hypertension, LDL cholesterol (<100 mg/dL), BMI, smoking, statins (intensity), and diabetes	0·747 (0·564–0·990)	1 (ref)	0·042
Multivariable adjusted for age, sex, family history of early coronary heart disease, smoking, and pharmacological treatments* at baseline	0·748 (0·562–0·997)	1 (ref)	0·048
Multivariable adjusted for age, sex, hypertension, LDL cholesterol (<100 mg/dL), BMI, smoking, statins (intensity), diabetes, and changes in weight and physical activity during follow-up	0·740 (0·558–0·982)	1 (ref)	0·035
Multivariable adjusted for all covariates used in the different models and randomisation order	0·719 (0·541–0·957)	1 (ref)	0·024

Data are hazard ratio (95% CI) or p value. All p values were calculated with Cox proportional-hazards models. The primary endpoint was a composite of myocardial infarction, revascularisation, ischaemic stroke, documented peripheral artery disease, and cardiovascular death events. BMI=body-mass index. *Statins, other lipid-lowering drugs, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, β-blockers, calcium antagonists, diuretics, insulin, oral antidiabetics, antiplatelets, and anticoagulants.

Table 3: **Hazard ratios for the main outcome of the Mediterranean diet and low-fat diet groups**

expected might support the hypothesis that the two diets had high efficacy in preventing cardiovascular recurrences and support the previous results of studies with low-fat diet versus control diets,[3–10] or with the Mediterranean diet in participants at high risk in primary prevention.[13]

Our study found that the superiority of the Mediterranean diet was higher in the male participants, suggesting that either there was not enough power in the female group or that sex is a factor in the dietary response. In this sense, our study was designed to represent the population with ischaemic heart disease and all patients who met the recruitment criteria were included, regardless of sex. Future studies should be created with sufficient power to unveil specific sex-related effects in women. Although other subgroup analyses also showed differences in the outcomes between diets, these findings were not primary endpoints of the study and should be taken as hypothesis-generating results.

Our study has limitations. First, this study included people with established coronary disease and, thus, the generalisability of our findings to other patient groups should be made with caution. Additionally, the study was done in a Mediterranean country with a higher acceptance for the Mediterranean lifestyle intervention. However, the low-fat diet study group was also well accepted by participants. The high acceptance of the Mediterranean diet in non-Mediterranean countries has been repeatedly reported;[35] therefore, our results should be generalised with caution to other geographical areas.

Our study also had some remarkable characteristics. First, the length of the study, which was challenging in itself, and even more so in a high-intensity dietary intervention. Second, the strict uniformity in the comprehensive characterisation, the medical treatment, and the dietary management of the cohort. This was done by planning the study as a single-centre study, which allowed the standardised high-intensity strategy, the homogenised and standardised care, and the thorough characterisation of the population. Finally, we were able to maintain follow-up through electronic medical records for 112 (85%) of 132 patients who abandoned the dietary intervention during the 7 years of the study, increasing the validity of the results of the intention-to-treat analysis. In summary, the CORDIOPREV study reports that a Mediterranean diet is superior to a low-fat diet in preventing major cardiovascular events in secondary prevention of cardiovascular disease.

Contributors

JD-L, FL-S, FP-J, PP-M, and JL-M contributed to the study conceptualisation. JD-L, JFA-D, JDT-P, EMY-S, OAR-Z, AC, FR-C, and JL-M were responsible for the data curation. JD-L, JFA-D, GMQ-N, and JL-M developed the formal analysis. JD-L, EMY-S, OAR-Z, AC, FL-S, FP-J, PP-M, and JL-M participated in funding acquisition. JD-L, JFA-D, GMQ-N, FF, AG-R, AMO-M, AIG-R, AIP-C, EMY-S, OAR-Z, AC, FP-J, PP-M, and JL-M participated in the clinical trial. JD-L, JFA-D, JDT-P, EMY-S, AC, OAR-Z, FP-J, PP-M, and JL-M were responsible for the methodology. JD-L, EMY-S, OAR-Z, AC, and JL-M handled the project administration. FR-C was responsible for resources. JD-L and JFA-D took responsibility for software. JD-L, PP-M, and JL-M supervised the entire project. JD-L, JFA-D, GMQ-N, EMY-S, AC, OAR-Z, FR-C, FP-J, PP-M, and JL-M took responsibility for validation process. EMY-S, OAR-Z, and AC developed the visualisation process. JD-L, JFA-D, and JDT-P were involved in writing the original draft. JD-L, JFA-D, LB, JMO, FP-J, PP-M, and JL-M were involved in writing, review, editing. JD-L, JFA-D, and JL-M have accessed and verified the data. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

JD-L reports a research grant from Instituto de Salud Carlos III (PI13/00023) and has received fees for lectures and educational activities from Novo-Nordisk, Amgen, Laboratorios Dr Esteve, Ferrer, Servier, Mylan–Viatrix, Instituto Cervantes, and the Spanish Society of Internal Medicine, all unrelated to this work. JFA-D reports research grants from Servicio Andaluz de Salud (B-0009-2017) and Insituto de Salud Carlos III (CM12/00202), and has received fees for lectures and educational activities from Bayer, Grunenthal Pharma, Laboratorios Dr Esteve, Ferrer, and Boehringer Ingelheim, all unrelated to this work. JDT-P has received fees for lectures and educational activities from Laboratorios Dr Esteve, Amgen, Sanofi, and the Spanish Society of Internal Medicine, all unrelated to this work, and is a board member of the Andalusian Society of Internal Medicine. FF has received fees for lectures and educational activities from Laboratorios Dr Esteve, Mylan, Novartis, Menarini, Servier, Novo-Nordisk, and Amgen, all unrelated to this work. AG-R reports a research grant from Consejería de Salud Junta de Andalucía (PI-0206-2013) and has received fees for lectures and educational activities from Laboratorios Dr Esteve and Instituto Cervantes, all unrelated to this work. EMY-S reports grants from Consejería de Salud-Junta de Andalucía (PC-0283-2017), Carlos III Health Institute (PI18/01822), and Servicio Andaluz de Salud-Junta de Andalucia (Nicolas Monardes Programme Contract C1-0005-2019). OAR-Z reports research grants from Ministerio de Ciencia e Innovacion (PI15/00733), Fundación para la investigación Biomédica de Córdoba (PI-0170-2018-FIB), and de Instituto de salud Carlos III (Miguel Servet Program CP19/00142). AC reports research grants from Instituto de Salud Carlos III (CP14/00114, PI19/00299, and DTS19/00007) and Ministerio de Economía y Competitividad (AGL2015-67896-P). FL-S has received fees for lectures and educational activities from Pfizer, Novartis, Mylan–Viatris, and Boehringer Ingelheim, all unrelated to this work. LB reports a research grant from AstraZeneca, has served on scientific advisory boards of Sanofi, Bayer, and AstraZeneca, has received speaker fees from Lilly, MSD–Boehringer, and AstraZeneca, and founded the spin-offs for Glycardial Diagnostics and Ivastatin Therapeutics S, all unrelated to this work. JMO has received research funding from the US Department of Agriculture on personalised nutrition, and from Archer Daniels Midland on probiotics, has served on the scientific advisory board or as a consultant for Nutrigenomix, the Predict Study, General Nutrition Centres, Weight Watchers, Metagenics, and Reckitt Group, all unrelated to this work. FP-J reports research grants from Instituto de Salud Carlos III (PI10/02412 and PI13/00619) and has received fees for lectures and educational activities from Mylan and Instituto Cervantes, unrelated to this work. PP-M reports research grants from Instituto de Salud Carlos III (PI13/00185, PI10/01041, and PI16/01777) and Consejería Salud Junta de Andalucía (PI058/10), and has received fees for lectures and educational activities for Novo-Nordisk, Boehringer Ingelheim, Amgen, Laboratorios Dr Esteve, MSD, Ferrer, Menarini, Servier, Mylan–Viatrix, Instituto Cervantes, and the Spanish Society of Internal Medicine, all unrelated to this work. JL-M reports research grants from Instituto de Salud Carlos III (PIE14/00005 and PIE14/00005), Ministerio de Ciencia e Innovación (PID2019-104362RB-I00, AGL2009-122270, PCIN-2016-084, and AGL2012/39615), Consejería de Salud Junta de Andalucia (PI0193/09), Ministerio de Ciencia e Innovación (AGL2015-67896-P), and Consejería de Economía, Innovación, Ciencia y Empleo (P20_00256 and CVI-7450), has received fees for lectures and educational activities from Novo-Nordisk, Sanofi, Amgen, Laboratorios Dr Esteve, MSD, and Instituto Cervantes, and has received consulting fees from Amgen and Sanofi, all unrelated to this work. All other authors declare no competing interests.

Data sharing

Collaborations with the Cordioprev Study are open to Biomedical Institutions, always after an accepted proposal for a scientific work. Depending on the nature of the collaboration, electronic data, hard copy data, or biological samples should be provided. All collaborations will be made after a collaboration agreement. Terms of the collaboration agreement will be specific for each collaboration, and the extent of the shared documentation (ie, deidentified participant data, data dictionary, biological samples, hard copy, or other specified data sets) will be also specifically set on the light of each work.

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